

MANUAL OF LABORATORY TESTS AND SERVICES

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STATE LABORATORY INSTITUTE

ESTABLISHED 1894

“Protecting the Public Health for over 100 Years”

305 South Street, Boston, MA 02130-3597, Phone: (617) 983-6200; Fax: (617) 983-6210,

Website: www.state.ma.us/dph/sli.htm

Our Commitment to You:

The Massachusetts State Laboratory Institute's (**SLI**) *Manual of Laboratory Tests and Services (MLTS)* describes our services and how to use them.

SLI provides comprehensive public health laboratory services for disease identification, surveillance, investigation and prevention. These services address priorities of public health in Massachusetts and complement clinical laboratory services. These core functions are part of the public health infrastructure and provide direct benefits to the health of our citizens.

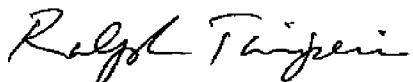
- Diagnostic testing
- Reference testing
- Laboratory-based surveillance
- Identification of the causes of outbreaks
- Health studies
- Training in laboratory methods
- Audiovisual training materials for laboratories
- Consultation of laboratory test interpretation and use
- Assurance of food safety
- Partner with the U.S. Centers for Disease Control and Prevention in the National Laboratory Response Network
- Regional early warning surveillance center for bioterrorism, food-borne outbreaks, antimicrobial resistance and emerging infectious diseases

SLI collaborates with local, state and federal agencies and the private sector to support disease prevention and treatment efforts across all areas of public health including family and child health, infectious and environmental disease prevention, quality assurance and control, substance abuse, food safety and occupational health.

Our number one job is to serve health and medical professionals by providing timely and accurate laboratory data, analysis and interpretation to support policy, planning and disease prevention and treatment actions that promote health and preserve wellness of our ultimate customers, the citizens of Massachusetts.

We challenge ourselves each day to improve, and to assure that the users of our services have the necessary laboratory support to solve routine as well as unusual health problems. We are committed to quality and encourage communication from you to inform us of how we are doing in meeting your needs. We want to continue to do those things that work well for you, and change those things that do not. The *MLTS* provides details of services and contact information to aid communication with our staff. We want to hear from you.

Very truly yours,



Ralph Timperi, MPH, Director, State Laboratory Institute
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Overview of the Manual:

The State Laboratory Institute's Manual of Laboratory Test and Services contains a complete listing of all tests performed at the State Laboratory Institute in an easy to read format. The manual describes how to collect and properly package good quality samples for testing to ensure safe transport to the laboratory.

All testing services provided by the State Laboratory Institute are found in Section 3 of the MLTS and are listed alphabetically by test name. Each test profile contains information pertaining to the collection, submission and analysis of samples. Note the information listed under Sample, Sample and Volume, Sample Container, Sample Test Kit, Shipping Requirements and any Special Instructions listed.

The index of tests in Section 4 contains an alphabetical listing of all tests performed along with the corresponding page numbers where specific test profiles can be found.

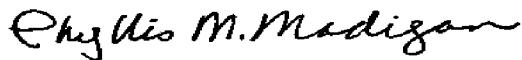
A listing of reportable diseases can be found in Section 2. This list should serve as a reminder to report results to the appropriate agency at the number designated. Results should be reported in a timely manner as noted.

Information regarding sample test kits can be found in Section 5 of the Manual. The information includes guidelines to avoid problems associated with sample collection and submission, a listing of sample test kits available for shipping specimens to the State Laboratory Institute, and how to order the test kits.

Section 6 of the Manual is devoted to packaging and shipping diagnostic specimens and infectious substances. This section contains information on the regulations as they pertain to dangerous or hazardous goods including infectious substances. You are directed to the websites to keep current with the latest changes.

We hope you will find this Manual to be a useful tool. We welcome your input and want to hear from you. What else would you like to see in the manual? If you need additional information or have questions, please call us. This manual can be found at the Bureau of Laboratory Sciences website, www.state.ma.us/dph/sli.htm. The manual will be kept updated continually in its electronic version.

Yours truly,



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Bureau of Communicable Disease Control (CDC), Program Contacts:

Communicable Disease Control, (Phone) 617-983-6550, (Fax) 617-983-6925

Division of Epidemiology and Immunization, (Phone) 617-983-6800, (Fax) 617-983-6840

Division of Tuberculosis Prevention and Control, (Phone) 617-983-6970, (Fax) 617-983-6990

HIV/AIDS Surveillance Program, (Phone) 617-983-6560, (Fax) 617-983-6580

Refugee and Immigrant Health Program, (Phone) 617-983-6590, (Fax) 617-983-6597

Division of Sexually Transmitted Disease Prevention, (Phone) 617-983-6940, (Fax) 617-983-6962

Communicable Disease Surveillance Program, (Phone) 617-983-6816, (Fax) 617-983-6813

Laboratory Programs and Sections:

Laboratory:	Phone Number:	Supervisor:	Phone Number:
Analytical Chemistry	(617) 983-6660	Paul Servizio	(617) 983-6653
Antimicrobial Resistance	(617) 983-6619	John Fontana	(617) 983-6619
Bacteriology	(617) 983-6600	Jacqueline Hankerson	(617) 983-6600
Chancroid	(617) 983-6606	Alan Borne	(617) 983-6606
Childhood Lead Screening	(617) 983-6665	Alan Rubin	(617) 983-6666
Chlamydia	(617) 983-6606	Jonelle Moloney	(617) 983-6606
Drug Analysis, Amherst	(413) 545-2601	Alan Stevenson	(413) 545-2601
Drug Analysis, Jamaica Plain	(617) 983-6622	Kevin McCarthy	(617) 983-6622
Enteric Bacteriology	(617) 983-6609	Robert Goldbaum	(617) 983-6609
Food Bacteriology	(617) 983-6610	Robert Goldbaum	(617) 983-6610
Gonorrhea	(617) 983-6606	Alan Borne	(617) 983-6606
HIV	(617) 983-6389	Arthur Kazianis	(617) 983-6389
Milk Bacteriology	(617) 983-6616	Joseph Mucci	(617) 983-6616
Pertussis Serology	(617) 983-6606	Michelle Ballard	(617) 983-6606
Pulsed Field Gel Electrophoresis	(617) 983-6612	Jonas Winchell	(617) 983-6612
Rabies	(617) 983-6387	Scott Hennigan	(617) 983-6391
Reference Bacteriology	(617) 983-6607	Ellen Silva	(617) 983-6607
Sexually Transmitted Diseases	(617) 983-6614	Albert Foley	(617) 983-6615
Syphilis Serology	(617) 983-6614	Michelle Ballard	(617) 983-6614
Tuberculosis	(617) 983-6373	Paul Elvin	(617) 983-6381
Vector-Borne Disease Surveillance	(617) 983-6796	Christopher Mores	(617) 983-6796
Virus Isolation	(617) 983-6382	Raymond Konomi	(617) 983-6382
Virus Serology	(617) 983-6396	Scott Hennigan	(617) 983-6391

Laboratory Services:

Services:	Supervisor:	Phone Number:
Bioterrorism Response Coordinator	Peter Belanger	(617) 983-6267
Laboratory Safety Director	Stephen Ridley	(617) 983-6205
Test Kit Preparation	Millie Govan	(617) 983-6643
Specimen Receiving	Benny Edge	(617) 983-6639
Sodium Sulfide Kits	Jane Gu	(617) 983-6654

Massachusetts Department of Public Health - Diseases Reportable by Healthcare Providers

The following diseases should be reported immediately by contacting the local board of health where the case resides or the Massachusetts Department of Public Health at (617) 983-6800 weekdays or at (617) 522-3700 (a 24 hour contact number in service 7 days a week):

Bacterial Meningitis (including suspect)	Poliomyelitis (including suspect)
Botulism (including suspect)	Rabies (Human only)
Diphtheria (including suspect)	Rubella, congenital and non-congenital (including suspect)
Haemophilus influenzae (invasive)	Tetanus (including suspect)
Hepatitis, Viral Type A in a foodhandler	Any Cluster / Outbreak of Illness
Measles (including suspect)	
Meningococcal Infection (invasive)	

Enteric Illness in a foodhandler should be reported ASAP to the local board of health where the case resides and the board of health where the case works.

Any cluster of work-related conditions, regardless of whether or not they are on the reportable list, shall be immediately reported by telephone or other electronic means to the MDPH, Occupational Health Surveillance Program at (617) 624-5632.

The following are other diseases reportable to local boards of health. Please report as soon as possible:

Amebiasis	Leptospirosis
Anthrax	Listeriosis
Babesiosis	Lyme Disease
Brucellosis	Malaria
Campylobacter Enteritis	Meningitis (viral, other)
Chickenpox (varicella)	Mumps
Cholera	Pertussis (Whooping Cough)
Cryptosporidiosis	Psittacosis
E coli O157: H7	Rabies (animal)
Encephalitis (specify type if known)	Reye Syndrome
Foodborne Poisonings:	Rheumatic Fever
Botulism	Rocky Mountain Spotted Fever
Paralytic Shellfish Poisoning	Salmonellosis (including typhoid and paratyphoid fevers)
Giardiasis	Shigellosis
Hansen's Disease	Toxic Shock Syndrome
Hemolytic Uremic Syndrome	Toxoplasmosis
Hepatitis, Viral Type A (non-foodhandler)	Trichinosis
Hepatitis, Viral Type B (acute or chronic)	Tularemia
Hepatitis, Viral Type C (nonA/nonB)	Yellow Fever
Hepatitis, Viral Unspecified	Yersiniosis
Kawasaki Disease	
Legionellosis	

There are mandatory statewide reporting requirements for all pediatric blood lead test results. Please report all pediatric blood lead levels of 25 ug/dL or greater within three days of testing and all other pediatric blood lead results within seven days of testing to the Childhood Lead Screening Laboratory at (617) 983-6668.

Requirements for reporting adult lead poisoning are as follows: report all blood lead results of 15 ug/dL or greater within one week to the Lead Registry, Division of Occupational Safety at (617) 969-7177.

For Cases of Emerging and Potentially Emerging Infections including the following call MDPH at (617) 983-6800:

Cyclospora	Hepatitis E
Dengue	Hepatitis G
Ehrlichiosis	Plague
Group A Streptococcus (invasive)	Viral Hemorrhagic Fevers
Hantavirus	

The following diseases are directly reportable to the Massachusetts Department of Public Health:

- HIV / AIDS - call (617) 983-6560 for information on how to report
- Sexually Transmitted Diseases call (617) 983-6952
 - Chancroid
 - Chlamydial Infections (genital)
 - Genital Warts
 - Granuloma Inguinale
 - Gonorrhea
 - Herpes, Neonatal (onset within 30 days after birth)
 - Lymphogranuloma Venereum
 - Ophthalmia Neonatorum
 - a) Gonococcal
 - b) Other Agents
 - Pelvic Inflammatory Disease
 - a) Gonococcal
 - b) Other Agents
- Syphilis
- Tuberculosis call 1-888-MASSMTB (24 hours / 7 days)
- Rabies Post-exposure Prophylaxis call (617) 983-6800

The following work-related diseases and injuries are reportable to the Massachusetts Department of Public Health. For information on reporting, contact the Occupational Health Surveillance Program at (617) 624-563.

- Occupational Lung Disease
 - a) Asbestosis
 - b) Silicosis
 - c) Beryllium Disease
 - d) Chemical Pneumonitis
 - e) Asthma caused by or aggravated by workplace exposures
- Work-related Heavy Metal Absorption
 - a) Mercury (blood > 15 ug/L; urine > 35 ug/g creatinine)
 - b) Cadmium (blood > 5 ug/L; urine > 5 ug/g creatinine)
- Work-related Acute Chemical Poisoning
 - a) Carbon Monoxide
 - b) Pesticide
 - c) Other
- Work-related Carpal Tunnel Syndrome
- Work-related injury to a person less than 18 years of age

For any questions regarding reportable diseases in Massachusetts contact the Communicable Disease Surveillance Program at (617) 983-6801.

LABORATORY TEST PROFILES:

Test Name:	<u>Acid Fast Bacilli (AFB)</u>
	See Mycobacteriology (TB) Smear and Culture (AFB).
Test Name:	<u>Adenovirus Antibody</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	Serodiagnosis of recent infection with this agent.
Test Includes:	Quantitative IgG antibody complement fixation testing using group antigens for human adenoviruses.
Significant Result:	Seroconversion or four-fold increase in titer.
Limitations:	Anticomplementary activity may interfere.
Availability:	As requested.
Turnaround Time:	2 to 7 days upon receipt of convalescent serum.
Sample and Volume:	3 mL of serum.
Forms Required:	Virus Serology Requisition Form.
Sample Test Kit:	Virus Serology Test Kit.
Sample Collection:	Acute and convalescent serum. See collection instructions in test kit.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments:	Additional tests recommended: Respiratory Virus Antibody; Adenovirus Culture.
Test Name:	<u>Adenovirus Culture</u>
Lab and Phone #:	Virus Isolation Laboratory (617) 983-6382
Limitations:	Asymptomatic shedding of adenoviruses frequently occurs in stool and throat.
Availability:	As requested.
Turnaround Time:	2 to 10 days.
Sample:	Eye swab, throat and/or nasopharyngeal swab (combined specimen preferred), stool, urine, cerebrospinal fluid, and tissue.
Forms Required:	Virus Isolation Requisition Form.
Sample Collection:	Call the laboratory for collection instructions.
Sample Test Kit:	Virus Isolation Kit.
Shipping Requirements:	Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments:	Note: Culture for additional viruses may be performed at the discretion of the laboratory. Serotyping of adenovirus isolates may be performed at CDC in outbreak situations.

Test Name:	Aeromonas species See Enteric Pathogens, Referred Culture.
Test Name:	<u>Alkalescens-dispar</u> (former name for E. coli O Antigen Groups 1 and 25) See Enteric Pathogens, Referred Culture.
Test Name:	<u>Amebiasis Serology</u> See CDC Serology-Bacterial/Fungal Protozoal.
Test Name:	<u>Anthrax</u> See <i>Bacillus anthracis</i> Culture.
Test Name:	<u>Arbovirus Culture, Avian</u>
Lab and Phone #:	Virus Isolation Laboratory (617) 983-6382
Use of Test:	To confirm selected PCR results.
Test Includes:	Isolation of Eastern Equine Encephalitis Virus (EEEV), West Nile Virus (WNV) or other viruses.
Turnaround Time:	3 to 7 days.
Sample and Volume:	Bird, dead, whole body, intact.
Forms Required:	West Nile Virus Requisition Form for reporting dead birds. The form is included in the sample collection test kit.
Sample Test Kit:	West Nile Kit.
Sample Collection:	See instructions included in kit.
Shipping Requirements:	Transport to the laboratory within 3 to 5 hours at refrigerator temperature. Use triple packaging system with ice pack for transporting by Courier Service.
Comments:	Apply a biohazard label and mark the outer container "Diagnostic Specimen" as appropriate.
	Information as to where the bird was found (exact location) must accompany the specimen.
Test Name:	<u>Arbovirus Culture, Human</u>
Lab and Phone #:	Virus Isolation Laboratory (617) 983-6382
Test Includes:	Isolation of Eastern Equine Encephalitis Virus (EEEV) or West Nile Virus WNV.
Limitations:	Isolates positive for virus other than EEEV or WNV may be forwarded to CDC for identification.
Availability:	As requested. Testing is restricted to illness onsets between May and October unless provided with a travel history to an endemic area. Consult the laboratory from November through April.
Turnaround Time:	3 to 7 days.
Sample and Volume:	Brain tissue, spinal cord, or 2 mL of aseptically collected cerebrospinal fluid.
Forms Required:	Virus Isolation/Arbovirus Requisition Form.
Sample Test Kit:	Provided by user.
Sample Collection:	Consult laboratory for details.
Shipping Requirements:	Transport to the laboratory within 24 hours at refrigerator temperature. Use triple

Comments:	packaging system with ice pack for transporting by Courier Service. Apply a biohazard label and mark the outer container "Diagnostic Specimen" as appropriate.
Additional tests recommended:	Serology preferred (Eastern Equine Encephalitis Antibody, West Nile Virus Antibody).
Note:	Culture for additional viruses may be performed at the discretion of the laboratory.
Test Name:	<u>Arbovirus Culture, Other</u>
Lab and Phone #:	Virus Isolation Laboratory (617) 983-6382
Test Includes:	Isolation of Eastern Equine Encephalitis Virus (EEEV) or West Nile Virus (WNV).
Limitations:	Isolates positive for virus other than EEEV or WNV maybe forwarded to CDC for identification.
Availability:	As requested.
Turnaround Time:	3 to 7 days.
Sample and Volume:	Varies, depending upon species. Call the laboratory for instructions.
Forms Required:	Virus Isolation/Arbovirus Requisition Form.
Sample Test Kit:	Provided by user.
Sample Collection:	Call the laboratory for instructions prior to collection.
Shipping Requirements:	Transport to the laboratory within 24 hours at refrigerator temperature. Use triple packaging system with ice pack for transporting by Courier Service. Apply a biohazard label and mark the outer container "Diagnostic Specimen" as appropriate.
Comments:	Additional tests recommended: Depending upon species, serology may be preferred (Eastern Equine Encephalitis Antibody, West Nile Virus Antibody). Note: Culture for additional viruses may be performed at the discretion of the laboratory.
Test Name:	<u>Arbovirus PCR, Avian</u>
Lab and Phone #:	Virus Isolation Laboratory (617) 983-6382 or (617) 983-6796
Test Includes:	Detects the presence of arboviral genetic material from Eastern Equine Encephalitis (EEEV) and West Nile Virus (WNV).
Limitations:	Detection of related viruses is not possible.
Availability:	Upon approval of Arborviral Program.
Turnaround Time:	2 to 4 days.
Sample and Volume:	Bird, dead, whole body, intact.
Forms Required:	West Nile Virus Requisition Form for reporting dead birds. The form is included in the sample collection kit.
Sample Test Kit:	West Nile Virus Kit.
Sample Collection:	Instructions for collecting samples are included in the test kit.
Shipping Requirements:	Transport to the laboratory within 3 to 5 hours at refrigerator temperature. Use triple packaging system with ice pack for transporting by Courier Service. Apply a biohazard label and mark the outer container "Diagnostic Specimen" as appropriate.
Comments:	Information as to where the bird was found (exact location) must accompany the specimen.

Test Name: Arbovirus PCR, Other
Lab and Phone #: Vector-Borne Disease Surveillance Laboratory (617) 983-6796
Use of Test: Detects the presence of arboviral genetic material from Eastern Equine Encephalitis (EEEV) and West Nile Virus (WNV).
Availability: As requested.
Turnaround Time: 2 to 4 days.
Sample and Volume: Varies, depending upon species. Call the Virus Isolation Laboratory at (617) 983-6382 for information on sample types and mosquito pools.
Sample Test Kit: Provided by user.
Sample Collection: Call the laboratory for instructions prior to collecting sample.
Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use triple packaging system for transporting by Courier Service. Apply a biohazard label and mark the outer container "Clinical Diagnostic Specimen" as appropriate.
Comments: **Note:** Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: Arbovirus Plaque Reduction Neutralization Test –Antibody (PRNT)
Lab and Phone #: Virus Isolation Laboratory (617) 983-6382
Use of Test: Titration of sera for determination of antibody specific to Eastern Equine Encephalitis Virus (EEEV) or West Nile Virus (WNV) and as confirmation of EIA results.
Availability: As requested. Testing is restricted to illness onsets between May and October unless provided with a travel history to an endemic area. Consult the laboratory from November through April.
Turnaround Time: 3 to 7 days.
Sample and Volume: 3 mL of serum; at least 1 mL of cerebrospinal fluid collected aseptically.
Forms Required: Virus Isolation /Arbovirus Requisition Form.
Sample Test Kit: Provided by user.
Sample Collection: Call the laboratory prior to sample collection for instructions.
Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments: **Additional tests recommended:** Serology (Eastern Equine Encephalitis Antibody, West Nile Virus Antibody).
Note: PRNT for additional antibody to other arboviral agents may be performed at the discretion of the laboratory.

Test Name: Arbovirus Plaque Reduction Neutralization Test –Virus (PRNT)
Lab and Phone #: Virus Isolation Laboratory (617) 983-6382
Use of Test: Confirmation of West Nile Virus or Eastern Equine Encephalitis Virus infection in isolates.
Availability: As requested. For humans, testing is restricted to illness onsets between May and October unless provided with a travel history to an endemic area. Consult the

Turnaround Time: laboratory from November through April.
Sample and Volume: 3 to 7 days.
Forms Required: Brain tissue, spinal cord, 2 mL of aseptically collected cerebrospinal fluid, birds, other mammalian specimens. Contact laboratory prior to specimen collection.
Sample Test Kit: Virus Isolation /Arbovirus Requisition Form.
Sample Collection: Provided by user.
Shipping Requirements: Call the laboratory for instructions prior to sample collection.
Comments: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Note: Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: *Arcobacter* species
See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: **Arsenic (Total), Hair** (for research purposes only).
Lab and Phone #: **Analytical Chemistry Laboratory** (617) 983-6653
Use of Test: To monitor possible toxic exposure to arsenic.
Method of Analysis: Acid digestion followed by graphite furnace atomic absorption spectroscopy.
Normal Range: Less than 0.5 µg/g
Toxic Concentrations: Concentrations of arsenic in chronic poisoning are generally in the 1 to 5 µg/g range, but may range as high as 40 µg/g.
Turnaround Time: 10 working days.
Sample Size: 1.0 gram
Sampling Instructions: Call laboratory for sampling instructions.
Forms Required: Proper documentation of provider, patient and sample.
Sample Container: Submit in a clean, zip-lock, plastic bag.
Shipping Requirements: Secure container, package, mark and label properly to avoid sample loss during delivery.

Test Name: **Arsenic (Total), Urine** (for research purposes only).
Lab and Phone #: **Analytical Chemistry Laboratory** (617) 983-6653
Use of Test: To measure acute exposure to arsenic.
Method of Analysis: Acid extraction followed by graphite furnace atomic absorption spectroscopy.
Normal Range: 0 to 20 µg/g creatinine
Turnaround Time: 10 working days.
Sample Volume: 100 mL
Sampling Instructions: Call laboratory for sampling instructions and container.
Forms Required: Proper documentation of provider, patient and sample.

Container: Trace metal-free, 8 ounce, urine specimen, collection container.
Collection: First void sample or an aliquot of a 24-hour urine collection. Measure and record the volume on the required paperwork.
Shipping Requirements: Sample must be refrigerated. Sample must be submitted to the laboratory for preservation within 24 hours of collection. Secure container, package, mark and label properly to avoid sample loss and ensure safe delivery.
Comments: All trace metal levels in urine are corrected for creatinine.

Test Name: [Aspergillosis Serology](#)
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: [Babesiosis, Serology](#)
See CDC Serology.

Test Name: [Bacillus anthracis Culture](#)
Lab and Phone #: Bacteriology Reference Laboratory (617) 983-6607
Use of Test: To rule out infection caused by *Bacillus anthracis*.
Test Includes: Subculture identification or isolation and identification of *B. anthracis* from lesions, eschars, tissue, blood, sputa, cerebral spinal fluid, etc. as well as environmental sources acceptable with prior consultation.
Normal Range: Negative for *B. anthracis*.
Contraindications: Patient does not have clinical evidence of anthrax.
Availability: Monday through Friday.
Turnaround Time: 2 to 5 days.
Sample: Pure subculture for identification or confirmation, primary specimen for isolation and identification, swab of lesion or eschar, tissue, blood culture or sputum.
Forms Required: Bacteriology Requisition Form.
Sample Container: Subculture: pure subculture growing on a suitable slanted substrate. Use a screw capped tube. Primary specimen: Commercial aerobic blood culture bottle for blood; sterile screw-capped tube collected with or without swab for all others. Legionella Transport Kit.
Sample Test Kit: Legionella Transport Kit.
Sample Collection: Use a blood culture bottle for blood. Use a dry swab and sterile tube to collect serous fluid, biopsy, sputum etc.
Shipping Requirements: Subculture or blood culture bottle: Use triple packaging system conforming to the USPS and/or DOT regulations. For primary specimen other than blood, same day delivery is recommended. Submit sample on coolant (Legionella Transport Kit may be used). If same day delivery is not available priority overnight transport is recommended. Specimen should be frozen and submitted in dry ice in a suitable container provided by user.

Test Name: [Bacillus cereus Culture, Food](#)
See *Bacillus cereus* Plate Count, Food.

Test Name:	<u>Bacillus cereus Culture, Stool</u>
	See Enteric Pathogens, Routine Culture.
	Note: Available through local health departments in Massachusetts only.
	Limited to outbreak situations wherein <i>B. cereus</i> has been isolated and quantified in significant numbers from related food samples.
Test Name:	<u>Bacillus cereus Plate Count, Food</u>
Lab and Phone #:	Bacteriology Food Laboratory (617) 983-6610
Use of Test:	To support epidemiologic evidence implicating food as a possible source of illness.
Special Instructions:	Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The laboratory should be notified by phone prior to submission. If the sample is a commercial food or if the suspect agent is chemical, the laboratory investigation is handled by the Environmental Chemistry Laboratory at the SLI or by the FDA. Culture of sample (Mannitol-egg yolk polymyxin agar, MYP plate count series), organoleptics.
Test Includes:	Culture of sample (Mannitol-egg yolk polymyxin agar, MYP plate count series), organoleptics.
Limitations:	Food will be examined for <i>B. cereus</i> only if the clinical and epidemiologic information is compatible with <i>B. cereus</i> foodborne disease.
Contraindications:	Food samples are examined from single or multiple cases of illness.
Availability:	Monday through Friday.
Turnaround Time:	2 to 7 days.
Sample and Volume:	More than 200 grams of implicated food.
Forms Required:	Sample Submission Forms are obtainable through the Bacteriology Food Laboratory (617) 983-6610, the MA Food Protection Program (617) 983-6712, and the local Board of Health.
Sample Container:	Original sample container as submitted by inspector or other sterile leak proof container.
Sample Collection:	Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information.
Shipping Requirements:	Transport or ship samples on ice in appropriate packagings.
Comments:	Additional tests recommended: <i>Bacillus cereus</i> Stool Culture.

Test Name:	<u>Bacterial Culture Identification</u>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	To identify an isolate for use in treatment selection and/or epidemiological studies.
Test Includes:	Identification of pure isolates determined to be of clinical significance as described in the history of the patient.
Limitations:	Identification of obligate anaerobes not performed.
Availability:	Monday through Friday.
Turnaround Time:	2 days to 1 month.
Sample:	Pure, actively growing culture on suitable agar slant.
Forms Required:	Bacteriology Requisition Form.
Shipping Requirements:	Use the triple packaging system. If pathogens are known or suspected, package,

mark, label and ship the sample according to DOT and/or USPS regulations for infectious substances.

Comments: **Additional tests recommended:** Prior laboratory work-up and submission of lab results are required.

Test Name:

Bacterial Typing, Pulsed Field Gel Electrophoresis (PFGE)

Lab and Phone #:

Molecular Diagnostic Laboratory (617) 983-6612

Use of Test:

To determine if isolates from different sources (i.e., patient and environmental isolates) are the same. Test is very discriminatory, and is primarily used in food related outbreaks. All confirmed isolates of enteric pathogens should be submitted to the Enteric Laboratory. (See Enteric Pathogens, Referred Culture.) Stool specimens from cases of suspected enteric infection should be submitted to the Enteric Laboratory. Enteric pathogens isolated from stool cultures will be analyzed by PFGE in outbreak associated cases. Isolates of non-enteric pathogens should be submitted to the Reference laboratory. (See Referred Culture Identification, Non-Enteric.) All isolates received by the PFGE Laboratory are stored at $\leq -70^{\circ}\text{C}$. This allows for the comparison of these strains to others submitted in the future.

Test Includes:

Bacterial strain typing using restriction endonuclease (enzyme) digestion of bacterial chromosomal DNA.

Interpretation of Results:

Contact the Epidemiology staff (617-983-6800) concerning results of foodborne investigations.

Limitations:

PFGE is not a diagnostic test. Results are used in conjunction with epidemiological findings that result from intense investigation. PFGE is performed on all unique cultures of *Salmonella* sp., *E. coli* O157:H7 and *Shigella sonnei*, that have been identified by the Enteric Laboratory. Currently, PFGE is also performed on unique cultures of *Listeria monocytogenes*. Accurate identification of all isolates must be confirmed prior to PFGE testing. Results are interpreted based on banding patterns.

Availability:

By special request only, Monday through Friday.

Turnaround Time:

1 to 2 weeks for pure cultures. Turnaround time is delayed if the isolate submitted is contaminated.

Sample:

Pure isolates must be received on agar slants.

Forms Required:

Bacteriology Requisition Form. Forms may be obtained by calling (617) 983-6600. Please write PFGE in under "other tests".

Shipping Requirements:

Ship at room temperature. Packaging and shipping of infectious substances must meet USPS, USDOT and/or IATA regulations as applicable.

Test Name:

Bartonella Serology

See CDC Serology.

Test Name:

Beta Lactamase Detection (GC)

See Gonorrhea Culture

Lab and Phone #:

Bacteriology Laboratory (617) 983-6606

Use of Test:

To determine the presence or absence of beta lactamase, the enzyme that destroys

penicillin. This test will also be performed on any isolates of *Moraxella catarrhalis* isolated from routine cultures in this laboratory.

Test Includes: Testing for the presence of the beta lactam-destroying enzyme, beta lactamase, by the Nitrocefin Direct Plate Method.

Limitations: A negative test does not verify penicillin sensitivity since an organism may not produce beta lactamase yet be resistant to penicillin. The test must be performed on pure cultures since organisms, other than the gonococcus, may also carry this trait.

Availability: Tuesday through Friday.

Turnaround Time: Same day on viable cultures, except for those received that are greater than 48 hours since restreak. Subcultures that are older than 48 hours upon receipt will be restreaked for testing on the following day.

Sample: Pure, viable culture of *Neisseria gonorrhoeae*.

Forms Required: Bacteriology Requisition Form. Forms may be obtained by calling 617-983-6600.

Sample Container: User provides the triple packaging system to meet all current regulatory shipping requirements for infectious substances.

Shipping Requirements: Ship 24-hour isolate on Thayer-Martin slant, at room temperature in shipping container approved for infectious substances to arrive the next day. Package, mark and label as infectious substance.

Comments: **Additional tests recommended:** Testing for penicillin susceptibility when the organism does not produce the enzyme.

Test Name: **Beta Lactamase Detection (*Haemophilus influenzae*, *Staphylococcus aureus*)**

Lab and Phone #: Bacteriology Reference Laboratory (617) 983-6607

Use of Test: To determine ability of the organism to produce beta lactamase. (Most useful for *H. influenzae* and *S. aureus*.)

Test Includes: Testing of aerobic bacteria for the presence of the beta lactam-destroying enzyme, beta lactamase.

Limitations: Some organisms do not produce beta lactamase but are penicillin resistant. The testing of obligate anaerobes is not performed.

Contraindications: Not done on mixed cultures.

Availability: Monday through Friday.

Turnaround Time: 1 to 2 days.

Sample: Pure culture of organism on an agar slant.

Forms Required: Bacteriology Requisition Form.

Sample Container: Provided by user.

Shipping Requirements: Package sample using triple packaging system. If the sample contains known pathogens, mark, label and ship the samples as an infectious substance.

Comments: **Additional tests recommended:** Minimum Inhibitory Concentration for some beta lactamase negative organisms.

Test Name: **Blastomycosis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name:	<u>Bordetella pertussis and other Bordetella spp. Culture</u>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	Diagnosis and confirmation of pertussis.
Test Includes:	Isolation and identification of <i>Bordetella pertussis</i> and other <i>Bordetella</i> spp. on patients whose age is less than 11 years, all cultures are acceptable regardless of cough duration. On patients whose age is 11 years or older, cultures are acceptable for the examination of <i>Bordetella pertussis</i> if the cough duration of the patient is less than 14 days. If cough duration is greater than 14 days, serology is the more appropriate diagnostic test.
Normal Range:	Recommended culture time: from time of cough onset to 14 days.
Limitations:	Results are not reliable if an outdated kit is used. An improperly obtained and/or cultured specimen taken at a less than the optimal stage of illness may not yield positive results.
Availability:	Monday through Friday.
Turnaround Time:	3 days for a presumptive report to 7 days for written report. All negative cultures are held for an additional 5 days of incubation and, if positive, are reported to the sender.
Sample:	Nasopharyngeal swab moistened in 1% CAS and rolled or swabbed over the slanted Charcoal Transport medium provided in the kit. If a commercially prepared Regan-Lowe deep is used the swab should be immersed in the medium and left in the culture tube. If a culture cannot be sent on the day it is taken, refrigerate the cultured specimen and send it on the next available day.
Forms Required:	Pertussis Culture Requisition Form.
Sample Test Kit:	Pertussis Culture Kit or commercial Regan-Lowe deep provided by the user.
Sample Collection:	Nasopharyngeal swab moistened in 1% CAS and rolled over the Charcoal Transport Slant after the specimen is taken. All material and complete directions are provided in the Pertussis Culture Kit.
Shipping Requirements:	Use triple packaging system. Same day delivery is recommended. Overnight priority mail with coolant is acceptable if same day delivery is not possible.

Test Name:	<u>Bordetella pertussis Serology</u>
Lab and Phone #:	Bacteriology Laboratory (617)-983-6600
Use of Test:	To determine the presence of IgG antibody to pertussis toxin, which is consistent with the presence of, or a recent infection with, <i>Bordetella pertussis</i> .
Test Includes:	Serologic, single serum, testing for the presence of IgG antibody to pertussis toxin.
Normal Range:	< 20 ug/mL IgG antibody to <i>Bordetella pertussis</i> toxin.
Limitations:	This test is not interpretable in children less than 11 years of age. In patients 11 years of age, or older, the results are most readily interpretable when the blood is drawn greater than 14 days and less than 56 days from cough onset. Results less than 20 μ g/mL may occur in individuals who have pertussis, particularly if the blood has been drawn less than 14 days after cough onset. Send only when cough duration is greater than 14 days.
Availability:	Monday through Friday.
Turnaround Time:	2 to 14 days. Repeat testing and time of year may effect how often test is performed.

Sample and Volume:	Serum (\geq 1 mL) or whole blood (5-10 mL) collected in a red top or Serum Separator Tube (SST). Serum is preferable to whole blood. Do not send both serology and culture specimen without prior laboratory approval.
Forms Required:	Pertussis Serology Requisition Form. Forms may be obtained by calling (617)-983-6600.
Sample Test Kit:	Pertussis serology specimen kit. Pertussis serology kits may be ordered by calling (617)-983-6640.
Sample Collection:	Collect 5 to 10 mL of whole blood in red top tube or SST. Use 13mm x100mm, or 16mm x 100mm tubes for collection. Allow the blood to clot at least 30 minutes. Separate the serum if a centrifuge is available.
Shipping Requirements:	Serum may be shipped at room temperature, cold or frozen. Whole blood must be maintained at a temperature between 2°C and 27°C. Use triple packaging system for shipping samples.

Test Name: *Borrelia burgdorferi*
See Lyme Disease, Western Blot IgM and IgG.

Test Name: **Botulism Culture, Food or Stool**
Lab and Phone #:
ALL BOTULISM TESTING IS REFERRED TO THE MASSACHUSETTS DIVISION OF EPIDEMIOLOGY. PLEASE CONTACT EPIDEMIOLOGY AT (617) 983-6800 FOR INSTRUCTIONS. PLEASE CONTACT THE ENTERIC BACTERIOLOGY LABORATORY AT (617) 983-6609 PRIOR TO SENDING SPECIMENS IN ORDER TO ALERT STAFF. INSTRUCT COURIER TO HAVE SWITCHBOARD CALL ENTERIC LAB UPON ARRIVAL.

Use of Test: To support a clinical diagnosis of botulism or infant botulism.
Test Includes: Culture for *Clostridium botulinum*. Confirmation and toxin typing by Mouse Neutralization Assay.
Limitations: Sufficient specimen amount must be submitted.
Contraindications: Test is performed only on patients who exhibit neurological symptoms suggestive of botulism or infant botulism, on patients who have consumed food suspected to contain botulinum toxin, or on foods highly suspected to contain botulinum toxin.
Availability: By special request only. Monday through Friday. Weekends in emergency situations.
Turnaround Time: Minimum 1 week.
Sample and Volume: 25 to 50 grams of stool. No preservative needed. 25 to 200 grams of implicated food samples are required for the test.
Sample Container: Sterile, leakproof container and insulated box with coolant. **DO NOT FREEZE.**
Shipping Requirements: Pack, mark and label sample as an infectious substance using a UN approved shipping container. "Select Agent" requirements apply. Shipment by courier as soon as possible is optimal. If necessary, ship overnight with coolant. **DO NOT FREEZE.**
Comments: **Additional tests recommended:** Botulism Toxin, Food or Stool and/or Botulism Toxin, Serum.

Test Name:	<u>Botulism Culture, Referred Culture</u>
Lab and Phone #:	ALL BOTULISM TESTING IS REFERRED TO THE MASSACHUSETTS DIVISION OF EPIDEMIOLOGY. PLEASE CONTACT EPIDEMIOLOGY AT (617) 983-6800 FOR INSTRUCTIONS. PLEASE CONTACT THE ENTERIC BACTERIOLOGY LABORATORY AT (617) 983-6609 PRIOR TO SENDING SPECIMENS IN ORDER TO ALERT STAFF.
Use of Test:	To support a clinical diagnosis of botulism or infant botulism.
Test Includes:	Confirmation by Mouse Neutralization Assay of culture suspected to be <i>Clostridium botulinum</i> . Toxin typing on positive cultures is also performed by Mouse Neutralization Assay.
Contraindications:	Test is performed only on cultures from patients who exhibit neurological symptoms suggestive of botulism or infant botulism, on cultures from patients who have consumed food suspected to contain botulinum toxin, or on cultures isolated from food(s) implicated in suspected cases of botulism.
Availability:	By special request only, Monday through Friday. Weekends in emergency situations.
Turnaround Time:	Minimum 1 week.
Sample:	Pure culture in screw-capped tube.
Forms Required:	Bacteriology Requisition Form. Forms may be obtained by calling (617) 983-6600.
Sample Container:	Use a UN approved shipping container for infectious substances Class 6.2.
Shipping Requirements:	Ship at room temperature using UN approved packagings. Package, mark, label and ship as infectious substance. "Select Agent" requirements apply. For more information, see last section in manual on packaging and shipping specimens.
Comments:	Additional tests recommended: Botulism Culture, Food or Stool and/or Botulism Toxin, Food or Stool and/or Botulism Toxin, Serum.

Test Name:	<u>Botulism Toxin, Mouse Neutralization Assay</u>
	See Botulism Toxin, Food or Stool and/or Botulism Toxin, Serum.

Test Name:	<u>Botulism Toxin, Food or Stool</u>
Lab and Phone #:	ALL BOTULISM TESTING IS REFERRED TO THE MASSACHUSETTS DIVISION OF EPIDEMIOLOGY. PLEASE CONTACT EPIDEMIOLOGY AT (617) 983-6800 FOR INSTRUCTIONS. PLEASE CONTACT THE ENTERIC BACTERIOLOGY LAB AT (617) 983-6609 PRIOR TO SENDING SPECIMENS IN ORDER TO ALERT STAFF. INSTRUCT COURIER TO HAVE SWITCHBOARD CALL ENTERIC LAB UPON ARRIVAL.
Use of Test:	To support a diagnosis of botulism, infant botulism, or to rule out botulism as part of a differential diagnosis.
Test Includes:	Toxin extraction from stool or food sample and testing for <i>Clostridium botulinum</i> neurotoxins A through G by Mouse Neutralization Assay.
Limitations:	Sufficient specimen amount must be submitted.
Contraindications:	Assay performed only on patients who exhibit neurological symptoms suggestive of botulism or infant botulism, on patients who have consumed food suspected to contain botulinum toxin, or on foods that are highly

Availability: suspected to contain botulinum toxin.
Turnaround Time: By special request only. Monday through Friday. Weekends in emergency situations.
Sample and Volume: Minimum 1 week.
Sample Container: 25 to 50 gs of stool, no preservatives or 25 to 200 g of implicated food.
Shipping Requirements: Sterile leakproof container. Insulated box with coolant. **DO NOT FREEZE.**
Comments: Pack, mark and label sample as an infectious substance, using a UN approved shipping container. "Select Agent" requirements apply. Shipment by courier as soon as possible is optimal. If necessary, ship overnight with coolant. **DO NOT FREEZE.**
Additional tests recommended: Botulism Culture, Stool or Food and/or Botulism Toxin, Serum.

Test Name: **Botulism Toxin, Serum**
Lab and Phone #: ALL BOTULISM TESTING IS REFERRED TO THE MASSACHUSETTS DIVISION OF EPIDEMIOLOGY. PLEASE CONTACT EPIDEMIOLOGY AT (617) 983-6800 FOR INSTRUCTIONS. PLEASE CONTACT THE ENTERIC BACTERIOLOGY LABORATORY AT (617) 983-6609 PRIOR TO SENDING SPECIMENS IN ORDER TO ALERT STAFF. INSTRUCT THE COURIER TO HAVE SWITCHBOARD CALL ENTERIC LABORATORY UPON ARRIVAL.

Use of Test: To support a diagnosis of botulism or infant botulism or to rule out botulism as a part of a differential diagnosis.

Test Includes: Testing serum for *Clostridium botulinum* neurotoxins A through G by Mouse Neutralization Assay

Limitations: Sufficient specimen must be submitted.

Contraindications: Assay performed only on patients who exhibit neurological symptoms suggestive of botulism or infant botulism or on patients who have consumed food suspected to contain botulinum toxin.

Availability: By special request only, Monday through Friday. Weekends in emergency situations.

Turnaround Time: Minimum 1 week.

Sample and Volume: 10 to 15 mL of serum; keep refrigerated. **DO NOT FREEZE.** PLEASE NOTE: In cases of suspected infant botulism, attending physician may feel that the drawing of blood may be too traumatic for the patient and, therefore, could limit any requested botulism testing to stool specimens and/or food samples.

Sample Container: Sterile serum vials. Insulated box with coolant.

Shipping Requirements: Package, mark and label sample as an infectious substance. "Select Agent" requirements apply. Shipment by courier as soon as possible is optimal. If necessary, ship overnight with coolant. **DO NOT FREEZE.**

Comments: **Additional tests recommended:** Botulism Culture, Referred Culture and/or Botulism Culture, Stool or Food and/or Botulism Toxin, Stool or Food.

Test Name:	<i>Brucella abortus</i>, Serology (non-specific for <i>Brucella abortus</i>)
Lab and Phone #:	Bacteriology Laboratory (617) 983-6600
Use of Test:	Positive test suggests a current infection; low titers may indicate a previous exposure to a related organism. Test is sensitive for <i>B. abortus</i> , <i>B. melitensis</i> , and <i>B. suis</i> only. See Interpretation of Results.
Test Includes:	Quantitative tube agglutination procedure for assaying titer of homologous agglutinins.
Interpretation of Results:	A 1:80 titer is considered a weakly positive serum while most patients with acute undulant fever demonstrate a titer of 1:320 or greater. Serum from patients with acute brucellosis demonstrate little or no antibody titer during the first 10 days of the disease. A negative result, therefore, does not preclude an active infection. Conversely, a positive result may not be diagnostic, since the serum may exhibit a rise in heterologous agglutinins due to a different febrile infection. This test is useful for screening purposes but should not be used as a substitute for conventional isolation and serological identification of the etiological agent.
Limitations:	<ol style="list-style-type: none"> 1. The major limitation is that of interpretation. See Interpretation of results, above. 2. It is advisable to run several serum specimens taken at different times to detect quantitative differences in agglutinin content. 3. There are many known antigenic similarities and cross-reactions with other antigens such as <i>Francisella tularensis</i>, <i>Proteus OX19</i>, <i>Vibrio cholerae</i>, and <i>Yersinia enterocolitica</i> serotype 9.
Availability:	Routinely run once every two weeks. Special arrangements for immediate testing can be made for high priority cases.
Turnaround Time:	Routinely, 2 weeks (see availability, above). Test procedure itself takes 48 hours to complete.
Sample and Volume:	Serum, collect 5 to 10 mL of whole blood aseptically from patient.
Sampling Instructions:	Allow blood to clot and obtain the syneresed serum with a Pasteur pipette. If serum is not free of erythrocytes, clarify by centrifugation. DO NOT HEAT. Specimen must be clear and free of visible fat. It must be free of excessive hemolysis and not bacterially contaminated.
Forms Required:	Bacterial Serology Requisition Form. Forms may be obtained by calling (617) 983-6600.
Sample Container:	Sealed serum tube.
Shipping Requirements:	Use triple packing system for shipping. Outer container should be an insulated box containing coolant. DO NOT FREEZE.

Test Name:	<i>Brucella Culture</i>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	To detect infections caused by <i>Brucella</i> spp.
Test Includes:	Subculture of blood, bone marrow, abscess or biopsy of liver or spleen for <i>Brucella</i> spp. Primary specimens for isolation and identification are acceptable with prior consultation.
Normal Range:	Negative for <i>Brucella</i> spp.
Limitations:	Blood cultures are only useful early in the acute phase of the disease.
Availability:	Monday through Friday.

Turnaround Time: Up to 3 weeks. Preliminary report may be obtained earlier.

Sample and Volume: 5 mL of blood, bone marrow, exudate, and tissue.

Forms Required: Bacteriology Requisition Form.

Sample Container: Pure subculture of organism; commercial aerobic blood culture bottle with CO₂ provided by the user; sterile vial for specimens other than blood.

Sample Collection: 5 mL of blood aseptically drawn and inoculated into 50 mL of culture broth (user provided).

Shipping Requirements: Subculture: Use triple packaging system for shipping infectious substances in accordance with postal regulations.

Primary Specimen: Rapid transport with same day delivery in a triple packaging system with a cold pack (Legionella Kit may be used); or sample may be frozen and packed in a suitable container with dry ice (provided by the user) if overnight delivery is anticipated.

Comments: **Additional tests recommended:** *Brucella abortus*, Serology.

Test Name: **Brucellosis**
See *Brucella abortus* Serology (non-specific for *Brucella abortus*) and/or *Brucella* Culture.

Test Name: **Cadmium, Urine** (for research purposes only).

Lab and Phone: **Analytical Chemistry Laboratory** (617) 983-6653

Use of Test: To measure acute cadmium exposure.

Method of Analysis: Acid extraction followed by graphite furnace atomic absorption spectroscopy.

Acceptable Range: 0 to 5 µg/g creatinine

Toxic Concentrations: > 5 µg/g creatinine

Turnaround Time: 10 working days.

Sample Volume: 100 mL

Sampling Instructions: Call laboratory for sampling instructions and container.

Forms Required: Proper documentation of provider, patient and sample.

Container: Trace metal free urine specimen collection container

Collection: First void sample or an aliquot of a 24-hour urine collection. Measure and record the volume on the required form.

Shipping Requirements: The sample must be refrigerated and must be submitted to the laboratory for preservation within 24 hours of collection. Secure container, package, mark and label properly to avoid sample loss and ensure safe delivery.

Comments: All trace metal levels in urine are corrected for creatinine.

Test Name: **Calicivirus PCR**

Lab and Phone #: **Virus Isolation Laboratory** (617) 983-6382

Use of Test: For outbreak investigations only, not for individual diagnosis.

Special Instructions: Samples are sent to CDC. Please call the Virus Isolation Laboratory prior to submitting specimens.

Limitations: Calicivirus may be detected in the stools of asymptomatic individuals. Some calicivirus types may not be detected with primers currently in use. Available patient information should be considered when interpreting test results. This

Sample: PCR-based test should be considered an investigational tool.
Forms Required: Stool (No additives or preservatives).
Sample Container: Virus Isolation Requisition Form.
Sample Collection: Sterile screw-capped container.
Sample Test Kit: Call the laboratory for sampling instruction.
Shipping Requirements: Provided by user.
Comments: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Additional tests recommended: Bacterial and other testing for causes of gastroenteritis may be appropriate based on incubation period, symptoms and other factors.

Test Name: California Encephalitis Antibody
Lab and Phone #: Sample sent to CDC.
Use of Test: Virus Serology Laboratory (617) 983-6396
Significant Result: To confirm or to rule out infection with this agent.
Limitations: Seroconversion or four-fold increase in titer.
Sample and Volume: Non-specific fluorescence may interfere.
Forms Required: 3 mL of serum, no additives.
Sample Test Kit: Virus Serology or CDC Requisition Form
Sample Collection: Virus Serology Kit.
Shipping Requirements: Acute and convalescent or convalescent serum only. See instruction in test kit.
Use triple packaging system for USPS. If the sample contains a known pathogen, use a triple packaging system. Label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: California Encephalitis IgM Antibody
Lab and Phone #: Sample sent to CDC.
Use of Test: Virus Serology Laboratory (617) 983-6396
Significant Result: Sample sent to CDC.
Limitations: Early serodiagnosis of an infection with this group of agents.
Sample and Volume: Presence of IgM indicates current or recent infection with this agent.
Forms Required: Cross-reactions occur with other members of the California encephalitis group, although the LaCrosse strain is the most likely agent to be encountered in the midwest region.
Sample Test Kit: 3 mL of serum.
Sample Collection: Virus Serology or CDC Requisition Form.
Shipping Requirements: Virus Serology Kit.
Acute serum collected 1 to 3 days after onset. See instructions in test kit.
Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the

container according to DOT and/or USPS regulations for infectious substances.

Test Name:	<u>California Encephalitis Virus Culture</u> See Arbovirus Culture. Samples Sent to CDC.
Test Name:	<u>Campylobacter Culture, Food</u> See <i>Campylobacter</i> Isolation, Food.
Test Name:	<u>Campylobacter Isolation, Food</u>
Lab and Phone #:	Bacteriology Food Laboratory (617) 983-6610
Use of Test:	To support epidemiologic evidence implicating a food as a possible source of illness.
Special Instructions:	Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The laboratory should be notified by phone prior to submission. If the sample is a commercial food the FDA, Food Protection Program handles the investigation. If the suspect agent is chemical, the investigation is handled by the Environmental Chemistry Laboratory at the SLI.
Test Includes:	Enrichment and culture of sample for <i>Campylobacter</i> species, Organoleptics.
Limitations:	Foods will be examined for <i>Campylobacter</i> only if the clinical and epidemiologic information is compatible with <i>Campylobacter</i> foodborne disease.
Contraindications:	Food samples are examined from single or multiple cases of illness.
Availability:	Monday through Friday.
Turnaround Time:	3 to 7 days.
Sample and Volume:	More than 200 grams of implicated food.
Forms Required:	Sample Submission Forms are obtainable through the Food Microbiology Lab (617) 983-6610, the MA Division of Food and Drugs, Food Protection Program (617) 983-6712, and local Board of Health.
Sample Container:	Original sample container as submitted by inspector or other sterile leak proof container.
Sample Collection:	Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information.
Shipping Requirements:	Transport or ship samples on ice in appropriate packagings.
Comments:	Additional Tests Recommended: Enteric Pathogens, Routine Culture.

Test Name:	<u>Campylobacter species</u> See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.
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Test Name: **Candidiasis Serology**
See CDC Serology-Bacterial/Fungal/Protozoal

Test Name: **CDC Culture Identification**
Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600
Test Includes: Any specimen or culture sent to CDC for specialized culture and for identification procedure. For *Streptococcus pneumoniae* serotyping, see Serotyping, *Streptococcus pneumoniae*, *Streptococcus pyogenes* (M and T Typing).
Availability: Monday through Friday.
Turnaround Time: Variable.
Sample: Swab in transport medium, blood or other body fluids, or pure culture isolate.
Forms Required: Bacteriology Requisition Form. Forms may be obtained by calling (617) 983-6600.
Shipping Requirements: Package and ship as an infectious substance according to the DOT, USPS or IATA regulations as applicable.

Test Name: **CDC Culture Identification**
Lab and Phone #: **Bacteriology Reference Laboratory** (617) 983-6607
Test Includes: Any specimen or culture sent to CDC for specialized culture and/or identification procedure. For *Streptococcus pneumoniae* serotyping, see Serotyping, *Streptococcus pneumoniae*, *Streptococcus pyogenes* (M and T Typing).
Availability: Monday through Friday.
Turnaround Time: Variable.
Sample: Pure culture isolate or primary specimen sent with prior consultation.
Forms Required: Bacteriology Requisition Form indicating justification for testing or request form for CDC submission, (617) 983-6607.
Shipping Requirements: Package and ship as an infectious substance according to the DOT, USPS or IATA regulations as applicable.

Test Name: **CDC Culture Identification, Mycobacteriology**
Lab and Phone #: **Mycobacteriology Laboratory** (617) 983-6381
Special Instructions: Please phone the laboratory in advance to request.
Turnaround Time: More than 30 days.
Forms Required: This non-routine test is not on the Mycobacteriology request form.
Sample Test Kit: TB Culture Kit.

Test Name: **CDC Serology-Bacterial/Fungal/Protozoal**
Lab and Phone #: **Bacteriology Reference Laboratory** (617) 983-6607
Test Includes: Qualitative and/or quantitative assays for various bacterial, fungal and protozoal agents performed by the CDC, Atlanta, GA. Specific agent desired must be written on requisition form.
Turnaround Time: 2 to 4 weeks.

Sample Volume: 1 mL of serum or cerebrospinal fluid.
Forms Required: Request form for CDC submission.
Sample Container: Provided by user.
Sample Collection: Routine blood draw or spinal tap.
Shipping Requirements: Use triple packaging system. Package, mark, label, and ship as infectious substance according to DOT, USPS or IATA regulations as applicable.
Comments: **Additional information needed:** paired sera are preferred for leptospirosis. Call the lab prior to submitting sera for malaria.

Test Name: **CDC Serology**
Lab and Phone #: Virus Serology Laboratory (617) 983-6396
Test Includes: Viral agent testing performed by the CDC in Atlanta, Puerto Rico or Fort Collins. Agents to be tested for, but not limited to, include Dengue fever, Ehrlichia, Yellow Fever, Hepatitis E and Lymphocytic Choriomeningitis (LCM) Interpretation included with report.
Significant Result: 2 to 4 weeks.
Turnaround Time: 3 - 5 mL of serum.
Sample and Volume: Virus Serology or CDC Requisition Form.
Forms Required: Virus Serology Kit.
Sample Test Kit: Usually acute and convalescent sera. See instructions in test kit.
Sample Collection: If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Shipping Requirements: **Additional information needed:** Relevant travel history, vaccine history, and date of onset must accompany sample
Comments:

Test Name: **Chagas' Disease Serology**
 See CDC Serology-Bacterial/Fungal/Protozoal

Test Name: **Chancroid, *Haemophilus ducreyi*, Culture**
 See *Haemophilus ducreyi*, Culture.

Test Name: **Chemical Contaminants, Food**
Lab and Phone: Analytical Chemistry Laboratory (617) 983-6653
Use of Test: Investigation of chemically induced food-borne illness.
Test Includes: Metals, organics, shellfish toxins, biogenic amines.
Turnaround Time: 5 to 10 working days
Sample: Food product and appropriate control samples.
Forms Required: Food Borne Illness Intake-Form as applicable.
Container: Varies with testing algorithm.
Collection: Call the laboratory for appropriate sampling, storage and transport procedures.
Shipping Requirements: Vary with testing algorithm.

Test Name: *Chlamydia psittaci* Antibody

Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396

Use of Test: Serodiagnosis of recent or current infection with this agent.

Test Includes: Quantitative IgG antibody CF testing for Chlamydia Psittaci.

Significant Result: Seroconversion or four-fold increase in titer.

Limitations: Anticomplementary activity may interfere.

Availability: Per requested.

Turnaround Time: 2 to 7 days upon receipt of convalescent serum.

Sample and Volume: 3 mL of serum.

Forms Required: Virus Serology Requisition Form.

Sample Test Kit: Virus Serology Kit.

Sample Collection: Acute and convalescent serum. See collection instructions in test kit.

Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: *Chlamydia trachomatis* Antibody

Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396

Use of Test: Serodiagnosis of recent or current infection with this agent.

Test Includes: IgG testing for *C. trachomatis* by indirect immunofluorescence assay.

Significant Result: Seroconversion or four-fold increase in titer.

Availability: As requested.

Turnaround Time: 2 to 7 days.

Sample and Volume: 3 mL of serum.

Forms Required: Virus Serology Requisition Form.

Sample Test Kit: Virus Serology Kit.

Sample Collection: Acute serum. See instructions in sample test kit. If positive, a convalescent serum is required for conclusive interpretation.

Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use the triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: *Chlamydia trachomatis*, Amplified Molecular Assay (AMA)

Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600

Use of Test: **TESTING IS AVAILABLE ONLY ON SPECIMENS FROM ASSIGNED CLINICS: Assigned clinics are specific sites selected to monitor disease prevalence throughout the Commonwealth.**

Selective screening of individuals at risk of Sexually Transmitted Diseases (STDs), including sexually active adolescents, contacts of STD patients, individuals with multiple sexual partners, and individuals exhibiting symptoms of an STD.

Test Includes:	An Amplified Molecular Assay.
Normal Range:	Negative for Chlamydia.
Limitations:	The only forensically acceptable Chlamydia test for medico-legal cases is a culture. AMA is not recommended for post-treatment assessment ("Test of Cure") and is not valid for sexual abuse/assault. In addition, specimens that may be tested are limited to those urogenital sites listed above; other sites are not approved by the FDA and will not be tested. The allowable time lapses between collection of the specimen, transport and receipt is critical and of limited length.
Availability:	Monday through Friday.
Turnaround Time:	1 to 4 days.
Sample:	Endocervical swab for females, urethral swabs for males, urines for males and females.
Forms Required:	Chlamydia Requisition Forms, supplied to assigned clinics by prior arrangement.
Sample Container:	Chlamydia Kits for transport of swab specimens. Transport outfits for urine supplied with collection kits. Kits are supplied to assigned clinics by prior arrangement.
Sample Test Kits:	Supplied to assigned clinics by prior arrangement.
Sample Collection:	In addition to the instructions provided in the kit, on-site training is provided to assigned clinics.
Shipping Requirements:	Direct courier delivery to Chlamydia Lab. Double packaging system used for transport.
Comments:	Additional tests recommended: Specimens from sites other than those listed as acceptable for this test may be tested for Chlamydia by culture method, Antigen Detection or by Direct Fluorescent Antibody (DFA) depending on collection site and circumstances of testing. These tests are available through private laboratories.

Test Name: *Cholera (Vibrio cholerae)*
 See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: *Clostridium botulinum, Culture*
 See Botulism Culture, Food or Stool and/or Botulism Culture, Referred Culture.

Test Name: *Clostridium perfringens Culture, Food*
 See *Clostridium perfringens* Plate Count, Food.

Test Name: *Clostridium perfringens Culture, Stool*
 See Enteric Pathogens, Routine Culture.
Note: Available through local Health Departments in Massachusetts only.
 Testing is limited to outbreak situations wherein *C. perfringens* has been isolated and quantified in significant numbers from related food samples.

Test Name:	<i>Clostridium perfringens</i> Plate Count, Food
Lab and Phone #:	Bacteriology Food Laboratory (617) 983-6610
Use of Test:	To support epidemiologic evidence implicating a food as a possible source of illness.
Special Instructions:	Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The laboratory should be notified by phone prior to submission. If the sample is a commercial food or if the suspect agent is chemical, the laboratory investigation is handled by the Environmental Chemistry Laboratory at the SLI or the FDA.
Test Includes:	Culture of sample (TSC plate count series), Organoleptics.
Limitations:	Foods will be examined for <i>C. perfringens</i> only if the clinical and epidemiologic information is compatible with <i>C. perfringens</i> foodborne disease.
Contraindications:	Food samples are examined from single or multiple cases of illness.
Availability:	Monday through Friday.
Turnaround Time:	2 to 7 days.
Sample and Volume:	More than 200 grams of implicated food.
Forms Required:	Sample Submission Forms are obtainable through the Food Microbiology Lab (617) 983-6610, MA Division of Food and Drugs, Food Protection Program (617) 983-6712, and the local Board of Health.
Sample Container:	Original sample container as submitted by inspector or other sterile leak proof container.
Sample Collection:	Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information. Do not freeze specimens suspected to contain <i>C. perfringens</i> , as this will diminish the number of organisms recovered on culture.
Shipping Requirements:	Transport or ship samples on ice.
Comments:	Additional test recommended: <i>Clostridium perfringens</i> Stool Toxin.

Test Name:	<u>Coccidioidomycosis Serology</u>
	See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name:	<u><i>Corynebacterium diphtheriae</i> Culture</u>
	See Diphtheria, Culture and In Vitro Toxigenicity.

Test Name:	<u>Cytomegalovirus Antibody</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	Serodiagnosis of recent or current infection with this agent.
Test Includes:	Quantitative IgG antibody CF testing for CMV.
Significant Result:	Seroconversion or four-fold increase in titer.
Limitations:	Anticomplementary activity may interfere.

Availability: As requested.
Turnaround Time: 2 to 7 days.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute and convalescent serum.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use the triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments: **Additional tests recommended:** Cytomegalovirus Culture.

Test Name: **Cytomegalovirus Culture**
Lab and Phone #: **Virus Isolation Laboratory (617) 983-6382**
Special Instructions: Only samples having prior approval of the Virus Isolation Laboratory or from state affiliated institutions are accepted for testing.
Availability: As requested.
Turnaround Time: 2 to 28 days for positive report; 28 days for negative report.
Sample: Stool, urine, cerebral spinal fluid, tissue, buffy coat.
Forms Required: Virus Isolation Requisition Form.
Sample Test Kit: Provided by user.
Sample Collection: Call laboratory prior to collection.
Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple Packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments: **Note:** Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: **Cryptococcosis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Cysticercosis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Diphtheria, Culture and In Vitro Toxigenicity**
Lab and Phone #: **Bacteriology Reference Laboratory (617) 983-6607**
Use of Test: Rule out *Corynebacterium diphtheriae* as causative agent of infection.
Test Includes: Culture for *Corynebacterium diphtheriae*. In Vitro toxin assay is performed on all isolates. The CDC, Atlanta, GA, performs PCR testing with prior

Normal Range: Negative for *C. diphtheriae*.

Limitations: Screen for *C. diphtheriae* only. Rule out Group A *Streptococcus*.

Contraindications: Lack of clinical evidence for infection with *C. diphtheriae*.

Availability: Monday through Friday.

Turnaround Time: 24-hour preliminary report, if suspicious; final report in 3 to 4 days.

Sample: Swab from the inflamed areas of the membranes in throat and nasopharynx, skin lesion and material from wounds removed by swab or aspiration.

Forms Required: Bacteriology Requisition Form.

Sample Container: Swab shipped dry in a sterile tube or in a special packet containing a desiccant such as silica gel provided by the user. A transport medium is not recommended.

Sample Collection: Swabs from infected membranes in throat and nasopharynx; skin lesion.

Shipping Requirements: Same day delivery is recommended. Use double packing system for courier. Overnight priority mail is recommended if same day delivery is not possible. Use triple packaging system for USPS.

Comments: **Additional tests recommended:** Direct smear for organisms of Vincent's angina and culture for group A *Streptococcus* and *Arcanobacterium haemolyticum*.

Test Name: **Eastern Equine Encephalitis Culture**
See Arbovirus listings

Test Name: **Eastern Equine Encephalitis Virus EIA**

Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396

Use of Test: Diagnosis of current infection with Eastern Equine Encephalitis Virus.

Test Includes: Qualitative IgM capture EIA and IgG indirect EIA testing.

Significant Result: Positive IgM; seroconversion with IgM and IgG.

Limitations: May cross-react with other arboviruses.

Availability: Routinely from May to October.

Turnaround Time: 2 to 7 days.

Sample and Volume: 3 mL of serum; at least 1 mL of cerebrospinal fluid collected aseptically.

Forms Required: Virus Serology /Arbovirus Requisition Form.

Sample Test Kit: Virus Serology Kit.

Sample Collection: **IgM:** Acute serum collected 1-3 days after onset; convalescent collected 9 or more days after onset may be necessary.

Shipping Requirements: **IgG:** Acute serum may be used for testing but convalescent collected 9 or more days after onset may be necessary.

Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Transport or ship samples at refrigerated temperatures. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **Echinococcosis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Ehrlichiosis, Serology**
See CDC Serology.

Test Name: **Entamoeba histolytica Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Enteric Pathogens, Referred Culture**
Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600
Test Includes: Genus and species identification of pathogenic isolates in the Enterobacteriaceae, Campylobacteraceae, and Vibrionaceae families (including *Salmonella* sp., *Shigella* sp., *Yersinia* sp., *E. coli* O157:H7, *Alkalescens* *dispar* {*E. coli* O-Antigen Groups 1 and 25}, *Campylobacter* sp., *Arcobacter* sp., *Vibrio* sp., *Aeromonas* sp., and *Plesiomonas shigelloides*). Tests include serotyping for *Salmonella*, *Shigella*, *Vibrio cholerae*, and *E. coli* O157:H7 isolates and biogrouping for *Yersina enterocolitica* isolates. Problematic isolates are submitted to CDC (Atlanta) for serotyping.

Limitations: 1. Serotyping is occasionally problematic if the culture has become rough and/or non-motile or is encapsulated.
2. Cultures of the Campylobacteriaceae must be submitted under more exacting conditions than those of the other organisms, i.e., pure culture is more important and timely submission is imperative. Sufficient growth must be obtained prior to sending sample to the State Laboratory.

Availability: Monday through Friday.

Turnaround Time: Usually 1 to 4 days for Enterobacteriaceae, 1 to 5 days for Campylobacteriaceae, and 3 to 5 days for Vibrionaceae.

Sample: Pure culture on appropriate medium (tubed media preferred).

Forms Required: Bacteriology Requisition Form. Forms may be obtained by calling (617) 983-6600.
Sample Container: Screw-capped tube.

Shipping Requirements: Ship in a UN approved container for shipment of infectious substances. See section on packaging and shipping specimens at the end of this manual. Media should be inoculated and incubated for 24 hours prior to shipping. Ship at ambient temperature. Pack, mark, label and ship sample as an infectious substance.

Test Name: **Enteric Pathogens, Routine Culture**
Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600
Use of Test: Screen for bacterial cause of diarrheal disease.
Test Includes: Culturing for *Salmonella*, *Shigella*, *Campylobacter*, *Arcobacter*, *Yersinia*, *Vibrio*, and/or *E. coli* O157:H7. Also available only through Massachusetts local Health Departments are the following: Culturing for

Bacillus cereus, for *Clostridium perfringens*, and/or for *Staphylococcus aureus*. These last three tests are limited to outbreak situations wherein the respective organism has been isolated and quantified in significant numbers from related food samples.

Normal Range:

Negative for enteric pathogens.

Limitations:

Stool specimens must be properly submitted, with transport containers not overfilled and with transport medium not removed. Specimen jars must be tightly closed and not leaking when received. Urine or other foreign material must not be mixed with the stool material. The time interval between collection of the specimen and receipt in the Lab must not be greater than 5 days.

Availability:

Monday through Friday. Weekends during significant outbreaks.

Turnaround Time:

Minimum 72 hours, maximum 1 week.

Sample and Volume:

Stool specimen. Rectal swab is acceptable but less desirable than stool. For Enteric collection/transport kit, fill with stool to indicated line on container (i.e. approximately 1 gram of stool). DO NOT OVERFILL. For fresh stool, use sterile screw-capped plastic specimen collection jar. For Cary-Blair Medium, inoculate a small amount of stool below the surface of the medium.

Forms Required:

Enteric Lab Stool-Submission Requisition Form, EC-1 found in enteric (stool) collection/transport kit provided. In outbreak situations, please indicate on the submission form specific outbreak identification and whether specimen is from a food-handler or other employee or from an attendee.

Sample Test Kit:

For all suspected pathogens except *Vibrio* species, use an Enteric Kit (for stool collection and transport). Kits may be ordered by calling (617) 983-6640. If necessary, a fresh stool on ice is acceptable if delivered on the same day as collected. For stools in which *Vibrio* species is suspected, submission of stool specimen in Cary-Blair Transport Medium at room temperature is recommended. Enteric collection/transport kits may be used if necessary for any *Vibrio* sp. (EXCEPT *V. cholerae*, which must be shipped in Cary-Blair Medium) as long as the specimens are delivered to the State Lab in a timely fashion. Sufficient moisture content of the specimen is the most important factor in maintaining the viability of *Vibrio* species. Please call the Enteric Bacteriology Lab at (617) 983-6609 prior to submission whenever *Vibrio cholerae* is suspected.

Sample Collection:

For Enteric collection/transport kit, see instructions in kit. For fresh stools, collect aseptically into sterile specimen collection jar.

Shipping Requirements:

For Enteric collection/transport kit or Cary-Blair Medium, ship at room temperature. For fresh stools only, ship or transport on wet ice or with coolant. Ship as "diagnostic specimen" using double packing system if transported by courier and triple packaging system if shipping by USPS.

Test Name:

Enterohemorrhagic *E. coli* (EHEC) O157:H7

See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: **Enterohemorrhagic E. coli (EHEC) NON-O157:H7**
See Shiga Toxin (Verotoxin) Assay.

Test Name: **Enterovirus Culture**
Lab and Phone #: **Virus Isolation Laboratory** (617) 983-6382
Use of Test: May detect coxsackieviruses, echoviruses, polioviruses and other viruses.
Limitations: Enteroviruses may be recovered from stools of asymptomatic patients; vaccine strain polioviruses may be recovered from stools of recently vaccinated individuals or their contacts. This test is usually performed in the context of an outbreak.

Availability: As requested.

Turnaround Time: 2 to 10 days for positive report or 10 days for negative report.

Sample: Throat swab, stool, cerebrospinal fluid, tissue, vesicular fluid.

Forms Required: Virus Isolation Requisition.

Sample Test Kit: Provided by user.

Sample Collection: Call the laboratory for sample collection instructions.

Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: **Note:** Culture for additional viruses may be performed at the discretion of the laboratory. Typing of poliovirus performed but serotyping of other isolates is performed only at CDC under special circumstances.

Test Name: **Erythema Migrans**
See Lyme Disease, Western Blot IgM and IgG.

Test Name: **Farmer's Lung Serology**
See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name: **Febrile Agglutinins**
See *Brucella abortus* Serology and/or *Francisella tularensis* Serology.

Test Name: **Fifth Disease**
See Parvovirus B19 IgM and IgG Antibody.

Test Name: **Filth Analysis (Quality Assurance)**
Lab and Phone #: **Bacteriology Food Laboratory** (617) 983-6610
Use of Test: To verify and identify the presence of extraneous foreign matter in food.
Special Instructions: Perishable samples should be submitted as soon as possible. Samples

Test Includes:	containing sharp objects (e.g., glass) should be handled with caution. Examination of foods and liquids for extraneous material such as insects, larvae, rodent droppings, glass or other foreign matter, Organoleptics.
Limitations:	Perishables should be examined within 2 days.
Availability:	Monday through Friday.
Turnaround Time:	1 to 2 days.
Sample and Volume:	Remainder of sample.
Forms Required:	Sample Submission Forms are obtainable through the Food Microbiology Lab (617) 983-6610, the MA Division of Food and Drugs, Food Protection Program (617) 983-6712, and the local Board of Health.
Sample Container:	Original sample container as submitted by inspector, or leak proof container.
Sample Collection:	Samples should be submitted in leakproof packaging or original containers.
Shipping Requirements:	Transport or ship non-perishable food at room temperature. Transport or ship perishable food on ice.

Test Name:	<u><i>Francisella tularensis</i> Culture</u>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	To screen for infection due to <i>Francisella tularensis</i> .
Test Includes:	Subculture identification isolated from blood, lesions, lymph nodes, sputum, gastric, aspirates, pleural fluid, etc. Positive results are phoned. Primary specimens for isolation and identification require prior consultation.
Normal Range:	Negative for <i>Francisella tularensis</i> .
Limitations:	Only screened for <i>Francisella tularensis</i> .
Contraindications:	Patients without clinical signs of tularemia.
Availability:	Monday through Friday.
Turnaround Time:	Up to 5 days.
Sample and Volume:	Bacterial subculture (pure) growing on slant. Primary specimens including lesion biopsy or swab, scrapings, lymph node tissue or aspirates, gastric aspirate, pleural fluid, etc. are acceptable with prior consultation. Culture of blood is not recommended as blood cultures seldom reveal the organism and when positive may take 7 to 9 days before positive. Septi-Chek Blood System inoculated with 5 to 30 mL of blood has proven best for isolation of the organism from blood. Serology may prove helpful.
Forms Required:	Bacteriology Requisition Form.
Sample Container:	Sterile vial, swab in Amies or Stuart's transport medium, Commercial blood bottle (Septi-Chek) provided by user.
Sample Collection:	Aseptic collection of tissue and body fluid.
Shipping Requirements:	Subculture: Triple packaging system conforming to postal regulations is provided by the user. For primary specimens, if using rapid transport (same day delivery) a Legionella Kit may be used. If overnight delivery is unavoidable the specimen should be frozen and packed in a suitable container with dry ice. If a pathogen is known or suspected, pack, mark, label and ship the sample as an infectious substance. "Select agent" rule applies. See last section in manual on packaging and shipping specimens.
Comments:	Additional tests recommended: See <i>Francisella tularensis</i> Serology.

Test Name:	<u>Francisella tularensis Serology</u>
Lab and Phone #:	Bacteriology Laboratory (617) 983-6600
Use of Test:	Positive test suggests a current infection; low titers may indicate a previous exposure to a related organism. See Interpretation of Results.
Test Includes:	Quantitative tube agglutination procedure for assaying titer of homologous agglutinins.
Interpretation of Results:	Paired specimens taken during both the acute phase and the convalescent phase are recommended. A rise in agglutination titer from the first to the second specimen is highly suggestive of tularemia. In the absence of paired specimens, a titer of 1:80 to 1:160 in the acute phase together with symptoms compatible with tularemia is suggestive of the disease. A significant titer is not attained until the second week of the disease and rises to a maximum in 4 to 6 weeks. A negative result does not preclude an active infection. Conversely, a positive result may not be diagnostic since the serum may exhibit a rise in heterologous agglutinins due to a different febrile infection. This test is useful for screening purposes but should not be used as a substitute for conventional isolation and identification of the etiological agent.
Limitations:	<ol style="list-style-type: none"> 1. The major limitation is that of interpretation. See Interpretation of Results above. 2. It is advisable to run several serum specimens taken at different times to detect quantitative differences in agglutinin content. 3. In some sera, cross-reactions may occur with <i>Brucella</i> antigens. Testing for both <i>Francisella</i> and <i>Brucella</i> antigens is helpful since the homologous system is of significantly higher titer than the heterologous system.
Availability:	Routinely run once every two weeks. Special arrangements for immediate testing can be made for high priority cases.
Turnaround Time:	Routinely, 2 weeks maximum (see availability, above). Test procedure itself takes 24 hours to complete.
Sample:	Serum (see volume and collection, below).
Sample Volume:	Collect 5 to 10 mL of whole blood aseptically from patient.
Forms Required:	Bacterial Serology Requisition Form. Forms may be obtained by calling (617) 983-6600.
Sample Container:	Sealed serum tube.
Sample Collection:	Allow blood to clot and obtain the syneresed serum with a Pasteur pipette. If serum is not free of erythrocytes, clarify by centrifugation. DO NOT HEAT. Specimen must be clear and free of visible fat. It must be free of excessive hemolysis and not bacterially contaminated.
Shipping Requirements:	Triple packaging system provided by user. Ship sample on coolant. DO NOT FREEZE. If sample is known to contain a pathogen, package, mark, label and ship the sample as an infectious substance. "Select agent" rule applies. See last section in manual on packaging and shipping specimens.

Test Name:	<u>Fungal Serology</u>
	See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **German Measles**
See Rubella Listings.

Test Name: **Gonorrhea Culture**
Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600
Use of Test: Screening and confirmation of *Neisseria gonorrhoeae*.
Test Includes:

DIAGNOSTIC TESTING ON PRIMARY CULTURES IS AVAILABLE ONLY ON SPECIMENS FROM ASSIGNED CLINICS: Assigned clinics are specific sites selected to monitor disease prevalence throughout the Commonwealth. Isolation and identification of *Neisseria* species recovered from primary cultures. Referred cultures for confirmation of *Neisseria gonorrhoeae* includes confirmatory testing on presumptive positive cultures (or oxidase positive cultures from clinics with limited testing capabilities) and genus and species identification on isolates referred for confirmation of *Neisseria gonorrhoeae*. Confirmation of antibiotic susceptibility patterns on isolates of *Neisseria gonorrhoeae* determined to be resistant. Beta lactamase testing by the Nitrocefin Direct Plate Method on all positive cultures. Susceptibility testing on all positive cultures: routinely six antibiotics tested (penicillin, tetracycline, ceftriaxone, ciprofloxacin, norfloxacin and ofloxacin); any isolate displaying any resistance or one that was submitted for a test of cure would initiate the testing of three additional antibiotics (cefoxitin, cefotaxime, and trobicin [spectinomycin]). Fluorescent Antibody (FA) confirmation of isolate from urogenital cultures that are not medico-legal cases. Confirmatory Cysteine Tryptose Agar (CTA) sugars on isolates from non-anogenital sources, on isolates from a child (<13 years old), and from medico-legal cases. Genus and species identification of any *Neisseria* species submitted as suspect for *Neisseria gonorrhoeae*.

Limitations: Since the estimated sensitivity of the culture is about 80% when all growth conditions are controlled, the major limitation is the quality of the specimen obtained and the handling of the specimen prior to receipt at the laboratory.

Availability: Monday through Friday.

Turnaround Time: 1 to 5 days.

Sample: Culture on Thayer Martin slant or plate: Primary culture on Thayer-Martin (TM) plate. Referred culture for confirmation on Thayer-Martin agar slant.

Forms Required: For primary cultures: A gonorrhea culture requisition form (GC-1) complete with all information requested. This form should be submitted to the State Laboratory along with culture. The primary culture forms are available by prior arrangement. For referred cultures: Use Bacteriology Form: FRMB1. Forms may be obtained by calling (617) 983-6600.

Sample Container: Use the using triple packaging container system to meet all current regulatory, diagnostic or infectious substance shipping requirements. Primary cultures should be maintained in a CO₂ environment (candle extinction jar, Gonopak, etc).

Sample Collection:	For Primary cultures: Swab from site of suspected infection streaked in a "Z" pattern (covering α to $\frac{1}{2}$ of the plate) to selective agar, cross-streaked and incubated at 35°-36°C, under 2-10% CO ₂ for a minimum of 16 hours before transporting.
Source:	The gonococcus is normally found in the columnar epithelial cells lining the endocervical canal and the urethra. A swab is used to collect material from exposed genital, anal and/or oropharyngeal sites. "Exposed" sites should be determined both on examination and interview of the patient. The cervix (if present) is the site of infection in the female and the site to be cultured routinely. In hysterectomized women, the urethra is the primary site of infection.
Incubation:	Primary cultures: Within 1 hour of inoculating the specimen, incubate the culture plate at 35°C, in a 2-10% CO ₂ atmosphere, for a minimum of 16 hours prior to transporting to the STD Laboratory.
Shipping Requirements:	Referred cultures: Place 24 hour isolate on Thayer-Martin slant. Ship at room temperature in a UN approved shipping container for infectious substances to arrive the next day. Package, mark, label and ship referred cultures as infectious substances. If possible, transport referred cultures by courier to the STD Laboratory. Primary cultures: Primary cultures in a CO ₂ environment (candle extinction jar or Gonopak, etc) must be delivered by same day courier to the STD Laboratory. If necessary, transport by First Class US Mail to arrive the next day.

Test Name:	<u>Gonorrhea, <i>Neisseria gonorrhoeae</i>, Culture</u> See Gonorrhea Culture.
Test Name:	<u>Gram Negative Bacilli</u> See Bacterial Culture Identification.
Test Name:	<u>Gram Negative Diplococci</u> See Gonorrhea Culture for Confirmation of Presumptive Positive Referred Cultures.
Lab and Phone #:	Bacteriology Laboratory (617) 983-6600
Use of Test:	To determine the presence or absence of organisms resembling <i>Neisseria gonorrhoeae</i> . Results of direct smear examination of exudate from an eye should always be interpreted in conjunction with culture results. Use of the direct smear in eye sources can give a rapid indication of the presence of intracellular gram negative diplococci, resembling <i>Neisseria gonorrhoeae</i> .
Test Includes:	Direct Smears: Examination of gram stained direct smear from <u>Eye</u> source only, submitted with culture from same source. See Gonorrhea Cultures for culture instructions. Prepare the culture from one side of the swab first and then prepare the slide from the remaining exudate.
Normal Range:	Organisms resembling <i>Neisseria gonorrhoeae</i> not seen.
Limitations:	Examination of gram stained direct smears does not confirm the presence

of viable organisms. The results should be used as an adjunct to the results of the culture and clinical presentation. Differentiation of *Neisseria* species can be determined only by reactivity with specified biochemicals.

Availability: Monday through Friday.

Turnaround Time: One day for direct smear.

Sample: Smear (the size of a dime) of swab from infected eye placed in the center of a 1x3 inch (12x75mm) microscope slide. Label frosted end of slide with patient's name and date of collection. Allow to air dry, place in slide transport container.

Forms Required: Gonorrhea Culture Requisition Form (GC-1) complete with all information requested. Mark the words "Smear and Culture" on the form. This form should be submitted along with the smear and culture. If Form GC-1 is not available, use Bacteriology Requisition Form: FRMB1. Forms may be obtained by calling (617) 983-6600.

Sample Container: Slide transport container provided by the user.

Sample Collection: Collect some of the exudate on the swab and place on microscope slide as described in Specimen and Volume.

Shipping Requirements: Send with accompanying culture to STD Lab. See Gonorrhea Culture for instructions to transport culture.

Test Name: **Gram Positive Bacilli**
See Bacterial Culture Identification.

Test Name: **Gram Positive Cocci**
See Bacterial Culture Identification.

Test Name: ***Haemophilus ducreyi*, Culture**
Due to the extreme growth requirements of this organism please call the STD Laboratories directly before submitting a specimen at (617) 983-6606.

Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600

Use of Test: To confirm *Haemophilus ducreyi*.

Test Includes: The isolation and identification of *Haemophilus ducreyi* from a primary culture, genus and species identification of isolates referred for confirmation of *Haemophilus ducreyi*.

Normal Range: Negative for *Haemophilus ducreyi*.

Limitations: Sensitivity of the culture, in known endemic areas, is only about 50%. The delayed growth patterns are conducive to overgrowth with mold due to the saturated atmosphere. The special media (with Vancomycin) are not commercially available and have a limited shelf life of 1 week.

Availability: Monday through Friday.

Turnaround Time: 5 to 10 days.

Sample: Swab of genital ulcer or aspirate of pus inoculated onto special media (Chocolate Agar with Vancomycin and/or Rabbit Blood Agar with Vancomycin). The media should contain both a source of hemin and serum and also incorporate vancomycin, which suppresses normal genital bacterial flora allowing the isolation of the slow growing *Haemophilus ducreyi*.

Forms Required:	Should the special media not be available, substitute GC Chocolate Agar (with 1% IsoVitaleX) as the primary culture plate. GC Chocolate agar, prepared according to a specific formulation has been shown to be more sensitive for the recovery of <i>Haemophilus ducreyi</i> than other formulations.
Sample Container:	Chancroid Requisition Form with all information completed. The Chancroid Requisition Form is available from the STD Lab at (617) 983-6606. If the Chancroid Requisition Form is unavailable, use Bacteriology Requisition Form: FRMB1. These forms may be obtained by calling (617) 983-6600.
Sample Collection:	Candle extinction jar or other system to provide a source of CO ₂ (e.g., GonoPak system), provided by the user.
Incubation:	For Primary cultures: Swab from the base of the ulcer (chancre) and up around the indurated edges. Inoculate media with swab in a "Z" pattern (covering α to $\frac{1}{2}$ of the plate), cross-streak the inoculum and incubate at 33°C, under 2-10% CO ₂ in an atmosphere that approximates 100% humidity, for a minimum of 48 hours before transporting.
Shipping Requirements:	Immediately after inoculation, place culture plate(s) into candle extinction jar with a wet paper towel on the bottom to obtain a water saturated atmosphere. Incubate at 33°C for 48 hours prior to moving from clinic site. If an incubation temperature of 33°C is not available, incubate at 35°C. higher temperatures will kill the organism; lower temperatures will retard growth and prolong the incubation time.
Comments:	For Primary Cultures: Deliver, by courier, to the STD Laboratory, Room 459. Use triple packaging system. For Referred Cultures: Using triple packaging system, ship 24-48 hour isolate on GC Chocolate Agar slant at room temperature in a UN approved shipping container for Class 6.2 infectious substances. Package, mark, label and ship in accordance with DOT or USPS regulations for next day arrival. Additional tests recommended: Concurrent testing should be performed to rule out the presence of etiological agents of other genital ulcers, especially syphilis and Herpes simplex.

Test Name:	<u><i>Haemophilus ducreyi</i>, Direct Smear</u>
Lab and Phone #:	Bacteriology Laboratory (617) 983-6600
Use of Test:	To detect the presence of <i>Haemophilus ducreyi</i> .
Test Includes:	Microscopic examination of gram stained direct smear for the presence of organisms resembling <i>Haemophilus ducreyi</i> .
Normal Range:	Organisms resembling <i>Haemophilus ducreyi</i> not seen.
Limitations:	Examination of gram stained direct smears does not confirm the presence of viable organisms. The results should be used as an adjunct to clinical presentation.
Availability:	Monday through Friday.
Turnaround Time:	1 to 2 days.
Sample:	Smear of swab from genital ulcer, chancre, or aspirate of pus, placed in the center of a 1x3 inch (12x75mm) microscope slide. Label frosted end of slide with patient's name and date of collection. Allow slide to air dry, place in slide transport container.

Forms Required:	Chancroid Requisition Form with all information completed. The Chancroid Requisition Form is available from the STD Lab at (617) 983-6606. If the Chancroid Requisition Form is unavailable, use Bacteriology Form: FRMB1. Forms may be obtained by calling (617) 983-6600.
Sample Container:	Slide transport container provided by user.
Sample Collection:	Ulcer (chancre) specimens, swab from the base of the ulcer (chancre) and up around the indurated edges. Bubo specimens, obtain aspirate and place on slide as described above in Sample.
Shipping Requirements:	Use the double packaging system (e.g. slide transport container in a padded envelope) to send the sample to the STD Lab., Rm. 459 by USPS or by courier.

Test Name:	<u><i>Haemophilus influenzae</i> Culture</u>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	To serotype isolate for use in treatment selection, beta lactamase production and/or epidemiological studies.
Test Includes:	Serotyping of <i>Haemophilus influenzae</i> .
Limitations:	Testing performed only on organisms isolated from normally sterile sites unless prior consultation is arranged.
Availability:	Monday through Friday.
Turnaround Time:	1 to 2 days.
Sample:	Pure young culture on chocolate agar slant.
Forms Required:	Bacteriology Requisition Form.
Shipping Requirements:	Ship in a UN approved container for Class 6.2 infectious substances. Ship at room temperature. Pack, mark, label and ship sample as an infectious substance in accordance with USPS and/ or DOT regulations.
Comments:	Additional tests recommended: Prior correct identification of <i>Haemophilus influenzae</i> is required.

Test Name:	<u><i>Hantavirus IgM and IgG</i></u>
Lab and Phone #:	Specimens Sent to CDC.
Use of Test:	Virus Serology Laboratory (617) 983-6396
Test Includes:	Diagnosis of Hantavirus Pulmonary Syndrome.
Significant Result:	Qualitative IgM capture EIA and IgG indirect EIA testing using the Sin Nombre Virus antigen.
Limitations:	Positive IgM combined with noncardiogenic pulmonary edema or bilateral interstitial infiltrates confirm Hantavirus Pulmonary Syndrome.
Availability:	May cross-react with other Hantaviruses.
Turnaround Time:	Once per week.
Sample and Volume:	Several weeks.
Forms Required:	3 mL of serum.
Sample Test Kit:	Virus Serology or CDC Requisition Form.
Sample Collection:	Virus Serology Kit.
Shipping Requirements:	Acute serum collected 1-3 days after onset. See sample test kit for instructions. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known

pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name:	<u>Hemorrhagic colitis <i>E. coli</i> O157:H7</u>
Lab and Phone #:	See Enteric Pathogens, Referred Culture AND/OR Enteric Pathogens, Routine Culture.
Test Includes:	
Special Instructions:	
Availability:	<u>Herpes Simplex Culture</u>
Turnaround Time:	Virology Laboratory (617) 983-6382
Sample:	Serotyping of herpes simplex types 1 and 2.
Forms Required:	Only samples having prior approval of the Virus Isolation Laboratory or from state affiliated institutions are accepted for testing.
Sample Test Kit:	As requested.
Sample Collection:	2 to 10 days for positive report. 10 days for negative report.
Shipping Requirements:	Lesion swab (oral, genital, skin), eye swab, cerebrospinal fluid, tissue, respiratory tract specimens.
Comments:	Virus Isolation Requisition Form.
	Virus Isolation Kit.
	See instructions in sample test kit.
	Transport to the laboratory within 24 hours at refrigerator temperatures. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
	Note: Culture for additional viruses may be performed at the discretion of the laboratory.
Test Name:	<u>Herpes Simplex Group Antibody</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	Serodiagnosis of recent or current infection with this agent.
Test Includes:	Quantitative complement fixation (CF) testing for IgG antibody to herpes simplex group antigen.
Significant Result:	Seroconversion or four-fold increase in titer.
Limitations:	Anticomplementary activity may interfere.
Availability:	As requested.
Turnaround Time:	2 to 7 days upon receipt of convalescent serum.
Sample and Volume:	3 mL of serum, no additives.
Forms Required:	Virus Serology Requisition Form.
Sample Test Kit:	Virus Serology Kit.
Sample Collection:	Acute and convalescent serum. See directions for sampling in test kit.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the

container according to DOT and/or USPS regulations for infectious substances.

Comments: **Additional tests recommended:** Herpes Simplex Culture.

Test Name:	<u>Histoplasmosis Serology</u>
	See CDC Serology–Bacterial/Fungal/Protozoal.
Test Name:	<u>HIV-1 Antibody Confirmation, OMT/Oral Fluid</u>
Lab and Telephone #:	HIV Laboratory (617) 983-6388 or (617) 983-6389
Use of Test:	Confirmation of HIV-1 antibody screening result for approved counseling and testing sites or for reference testing and epidemiologic studies.
Test Includes:	Enzyme-linked immuno-blot (Western Blot) analysis for detection of antibody to specific viral proteins of HIV-1. HIV-2 testing is not available for oral fluid specimens.
Limitations:	Only approved sites may submit samples.
Contraindications:	Must comply with Massachusetts General Laws regarding HIV testing (Chapter 111, section 70 f). The HIV-1, Western blot, will not be performed without repeatedly reactive HIV-1 EIA results.
Availability:	Monday through Friday, 9:00am to 5:00pm.
Turnaround Time:	One week.
Sample Volume:	Minimum of 1 mL OMT/oral fluid.
Forms Required:	HIV Laboratory Oral Fluid Sample Submission Form.
Sample Container:	OraSure oral specimen collection device must be used.
Sample Test Kit:	Use HIV single mailing or courier or HIV multiple mailing or courier kits.
Sample Collection:	Use an OraSure oral specimen collection device. Specimens received with less than the minimum required volume are rejected. Submission must include bar-coded label as the only identifier. The laboratory will not test any specimen received with a client's name, birth date or other personal identifiers.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Patient Preparation:	Informed consent for HIV testing must be obtained.
Comments:	Additional Information Required: Specimen collection date must appear on the sample submission form.

Test Name:	<u>HIV-1 Antibody Confirmation, Serum</u>
Lab and Telephone #:	HIV Laboratory (617) 983-6388 or (617) 983-6389
Use of Test:	Confirmation of HIV-1 antibody screening result for approved counseling and testing sites or for reference testing and epidemiologic studies.
Test Includes:	Enzyme-linked immuno-blot (Western Blot) analysis for detection of antibody to specific viral proteins of HIV-1.
Limitations:	Only approved sites may submit samples.
Contraindications:	Must comply with Massachusetts General Laws regarding HIV testing (Chapter

111, section 70 f). The HIV-1, Western blot, will not be performed without repeatedly reactive HIV-1 EIA results.

Availability: Monday through Friday, 9:00am to 5:00pm.

Turnaround Time: One week.

Sample and Volume: Minimum of 1 mL of serum or plasma.

Forms Required: HIV Laboratory Serum Sample Submission Form.

Sample Container: Use only serum separator tube without additives.

Sample Test Kit: Use HIV single mailing or courier or HIV multiple mailing or courier kits.

Sample Collection: Routine blood draw. A serum separator tube without additives is required.

Shipping Requirements: The specimen must arrive centrifuged with bar-coded label as the only identifier. The laboratory will not test any specimen received with a client's name, birth date or other personal identifiers.

Patient Preparation: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: Informed consent for HIV testing must be obtained.

Additional Information Required: Specimen collection date must appear on the Sample Submission form.

Test Name: **HIV-1 Antibody Screen, OMT/ Oral Fluid**

Lab and Telephone #: **HIV Laboratory** (617) 983-6388 or (617) 983-6389

Use of Test: To determine antibody status to HIV-1, the causative agents of AIDS, at approved counseling and testing sites and for reference testing and epidemiological studies.

Test Includes: Qualitative testing by a commercial enzyme immunoassay EIA procedure. This EIA procedure has the ability to detect antibody to HIV-1. HIV-1 Western Blot is performed if EIA is repeatedly reactive. HIV-2 testing is not available for oral fluid specimens.

Limitations: **Only approved sites may submit specimens.** Does not determine presence of the HIV virus. Test may be non-reactive for several weeks following exposure or in the final stages of AIDS.

Contraindications: Must comply with Massachusetts General Laws regarding HIV testing (Chapter 111, section 70 f).

Availability: Monday through Friday, 9:00am to 5:00pm.

Turnaround Time: One week.

Sample Volume: Minimum of 1 mL of OMT/oral fluid.

Forms Required: HIV Laboratory oral fluid Sample Submission Form.

Sample Container: OraSure oral specimen collection device must be used.

Sample Test Kit: Use HIV single mailing or courier or HIV multiple mailing or courier kits.

Sample Collection: Use an OraSure oral specimen collection device. Specimens received with less than the minimum required volume are rejected. Submission must include the bar-coded label as the only identifier. The laboratory will not test any specimen received with a client's name, birth date or other personal identifiers.

Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple

Patient preparation:	packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances. Informed consent must be obtained.
Comments:	Additional information required: Specimen collection date must appear on the sample submission form.
Test Name:	<u>HIV-1 Antibody Screen, Serum</u>
Lab and Telephone #:	HIV Laboratory (617) 983-6388 or (617) 983-6389
Use of Test:	Antibody status to HIV-1, a causative agent of AIDS, for approved counseling and testing sites or for reference testing and epidemiological studies.
Test Includes:	Qualitative testing by a commercial enzyme immunoassay EIA procedure. This EIA procedure has the ability to detect antibody to HIV-1. HIV-1 Western Blot is performed if EIA is repeatedly reactive. If HIV-1 Western Blot is non-reactive or indeterminate, HIV-2 testing will be performed.
Limitations:	Only approved sites may submit specimens. Does not determine presence of HIV virus. Test may be non-reactive for several weeks following exposure or in final stages of AIDS.
Contraindications:	Must comply with Massachusetts General Laws regarding HIV testing (Chapter 111, section 70 f).
Availability:	Monday through Friday, 9:00am to 5:00pm.
Turnaround Time:	One week.
Sample and Volume:	Minimum of 1mL of serum or plasma.
Forms Required:	HIV Laboratory Serum Sample Submission Form.
Sample Container:	Mailing container provided by State Laboratory Institute.
Sample Test Kit:	Use HIV single mailing or courier or HIV multiple mailing or courier kits.
Sample Collection:	Routine blood draw. Serum separator tube required. No additive is necessary. Specimen must arrive centrifuged with bar-coded label as the only identifier. The laboratory will not test any specimen received with a client's name, birth date or other personal identifiers.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances. Informed consent must be obtained.
Patient preparation:	
Comments:	Additional information required: Specimen collection date must appear on submission form.

Test Name:	<u>HIV-2 Antibody Confirmation, Serum Only</u>
Lab and Telephone #:	HIV Laboratory (617) 983-6388 or (617) 983-6389
Use of Test:	Confirmation of HIV-2 antibody screening result for approved counseling and testing sites or for reference testing and epidemiologic studies.
Test Includes:	Enzyme-linked immuno- blot (Western Blot) analysis for detection of antibody to specific viral proteins of HIV-2.

Limitations:	Only approved sites may submit specimens.
Contraindications:	Must comply with Massachusetts General Laws regarding HIV testing (Chapter 111, section 70 f). The HIV-2, Western Blot, will not be performed without repeatedly reactive HIV-2 EIA results.
Availability:	Monday through Friday, 9:00am to 5:00pm.
Turnaround Time:	One week.
Sample Volume:	Minimum of 1 mL of serum or plasma.
Forms Required:	HIV Laboratory Serum Sample Submission Form.
Sample Container:	Mailing canisters provided by State Laboratory Institute.
Sample Test Kit:	Use HIV single mailing or courier or HIV multiple mailing or courier kits.
Sample Collection:	Routine blood draw. Serum separator tube required with no additive necessary. Specimen must arrive centrifuged with bar-coded label as the only identifier. The laboratory will not test any specimen received with a client's name, birth date or other personal identifiers.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances. Informed consent for HIV testing must be obtained.
Patient Preparation:	Additional information required: Specimen collection date must appear on submission form. Counselor must indicate HIV-2 risk on submission form.
Comments:	

Test Name:	<u>HIV-2 Antibody Screen, Serum Only</u>
Lab and Telephone #:	HIV Laboratory (617) 983-6388 or (617) 983-6389
Use of Test:	Antibody status to HIV-2, a causative agent of AIDS, for approved counseling and testing sites or for reference testing and epidemiologic studies.
Test Includes:	Qualitative testing by a commercial enzyme immunoassay EIA procedure. This EIA procedure has the ability to detect antibody to HIV-2. HIV-2 Western Blot is performed if EIA is repeatedly reactive. If HIV-1 Western Blot is non-reactive or indeterminate, HIV-2 screening will be performed.
Limitations:	Only approved sites may submit specimens. Does not determine presence of HIV virus. Test may be non-reactive for several weeks following exposure or in final stages of AIDS. (FDA approval for use with serum specimens only)
Contraindications:	Must comply with Massachusetts General Laws regarding HIV testing (Chapter 111, section 70 f).
Availability:	Monday through Friday, 9:00am to 5:00pm.
Turnaround Time:	One week.
Sample Volume:	Minimum of 1 mL of serum or plasma.
Forms Required:	HIV Laboratory Serum Sample Submission Form.
Sample Container:	Mailing canisters provided by State Laboratory Institute.
Sample Test Kit:	Use HIV single mailing or courier or HIV multiple mailing or courier kits.
Sample Collection:	Routine blood draw. Serum separator tube required with no additive necessary. Specimen must arrive centrifuged with bar-coded label as the only identifier. The laboratory will not test any specimen received with a client's name, birth date or other personal identifiers.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple

packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances. Informed consent must be obtained.

Patient preparation:
Comments:

Additional Information Required: Specimen collection date must appear on submission form. Counselor must indicate HIV-2 risk on submission form.

Test Name: **Influenza A, Rapid Test**

Lab and Phone #: **Virus Isolation Laboratory (617) 983-6382**

Test Includes: Identification of specimens positive for influenza A antigen.

Availability: Performed on Fridays or days preceding holidays from October through March. Contact the laboratory prior to submitting samples from April to September.

Turnaround Time: 1 day for preliminary positive report. Positives are confirmed by conventional culture and subtyping.

Sample: Throat swab, nasopharyngeal swab, bronchial wash or other respiratory specimen.

Forms Required: Influenza Requisition Form.

Sample Test Kit: Influenza Test Kit. **Call (617) 983-6848 to order kits.**

Sample Collection: See instructions in influenza test kit.

Shipping Requirements: Transport to the laboratory within 24 hours on ice pack included with kit or at refrigerator temperatures. Use triple packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: **Note:** As this procedure is not as sensitive as conventional tissue culture, specimens testing negative are not reported until conventional culture results are finalized. Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: **Influenza Inhibition of Hemagglutination**

Lab and Phone #: **Virus Isolation Laboratory (617) 983-6382**

Test Includes: Subtyping of isolates exhibiting hemadsorption.

Limitations: Occasionally, frozen isolates testing positive off-site do not grow upon reinoculation. Isolates unable to be subtyped are tested for parainfluenza virus and/or are sent to CDC.

Availability: As requested from October through March. Contact the laboratory prior to sending samples to the laboratory from April through September.

Turnaround Time: 2 to 7 days.

Sample: Isolate exhibiting hemadsorption or preliminary positive immunofluorescence result.

Forms Required: Virus Isolation Requisition Form.

Sample Test Kit: Provided by user.

Sample Collection: Call Laboratory for sample collection instructions.

Shipping Requirements: If frozen, transport to lab on dry ice. If tube culture is to be submitted, call the laboratory prior to shipment. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **Influenza Rapid Culture**

Lab and Phone #: **Virus Isolation Laboratory (617) 983-6382**

Test Includes: Isolation and typing of influenza virus by shell vials.

Availability: As requested from October through March. Contact the laboratory prior to sending samples from April through September.

Turnaround Time: 1 to 2 days for preliminary positive report. Positives are confirmed by conventional culture and subtyping.

Sample: Throat swab, nasopharyngeal swab, bronchial wash or other respiratory specimen.

Forms Required: Influenza Requisition Form.

Sample Test Kit

Sample Collection: See instructions in influenza test kit.

Shipping Requirements: Transport to the laboratory within 24 hours on ice pack included with kit or at refrigerator temperatures. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: **Note:** As this procedure is not as sensitive as conventional tissue culture, specimens testing negative are not reported until conventional culture results are finalized. Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: **Influenza Type A Antibody**

Lab and Phone #: **Virus Serology Laboratory (617) 983-6396**

Use of Test: Serodiagnosis of recent or current infection with this agent.

Significant Result: Seroconversion or four-fold increase in titer.

Test Includes: Quantitative complement fixation testing for IgG antibody to influenza, type A.

Limitations: Anticomplementary activity may interfere.

Availability: As requested.

Turnaround Time: 2 to 7 days upon receipt of convalescent serum.

Sample and Volume: 3 mL of serum.

Forms Required: Virus Serology Requisition Form.

Sample Test Kit: Virus Serology Kit.

Sample Collection: Acute and convalescent serum. See instructions in test kit.

Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer

container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments:

Additional tests recommended: Influenza Culture.

Test Name:

Influenza Type B Antibody

Lab and Phone #:

Virus Serology Laboratory (617) 983-6396

Use of Test:

Serodiagnosis of recent or current infection with this agent.

Test Includes:

Quantitative complement fixation testing for IgG antibody to influenza, type B.

Significant Result:

Seroconversion or four-fold increase in titer.

Limitations:

Anticomplementary activity may interfere.

Availability:

As requested.

Turnaround Time:

2 to 7 days upon receipt of convalescent serum.

Sample and Volume:

3 mL of serum.

Forms Required:

Virus Serology Requisition Form.

Sample Test Kit:

Virus Serology Kit.

Sample Collection:

Acute and convalescent serum. See instructions for collection in test kit.

Shipping Requirements:

Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments:

Additional tests recommended: Influenza Culture.

Test Name:

Influenza/Parainfluenza Conventional Culture

Lab and Phone #:

Virus Isolation Laboratory (617) 983-6382

Test Includes:

Isolation of influenza virus utilizing Hemadsorption assay.

Availability:

As requested from October through March. Contact the laboratory prior to sending samples from April through September.

Turnaround Time:

4 to 12 days for a positive report. 10-12 days for negative report.

Sample:

Throat swab, nasopharyngeal swab, bronchial wash or other respiratory specimens.

Forms Required:

Influenza Requisition Form.

Sample Test Kit:

Influenza Test Kit. **Call (617) 983-6848 to order kits.**

Sample Collection:

See instructions included in test kit.

Shipping Requirements:

Transport to the laboratory within 24 hours on ice pack included with kit or at refrigerator temperatures. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments:

Note: Culture for additional viruses may be performed at the discretion of the laboratory. Hemadsorption positive isolates are tested by the inhibition of hemagglutination test for confirmation of influenza and subtyping.

Test Name: **Lead, Dust Wipes** (Samples submitted by licensed Lead Inspectors only)

Lab and Phone #: **Analytical Chemistry Laboratory** (617) 983-6654

Use of Test: To determine the efficacy of and monitor post abatement clean up.

Method of Analysis: Acid extraction followed by flame atomic absorption spectroscopy.

Allowable Limits: Floor 200 µg/ft²,
Window Sill 500 µg/ft²,
Window Well 800 µg/ft²

Turnaround Time: 3 to 5 working days

Forms Required: Dust Sample Submission Form, complete with documentation of provider, occupant of dwelling, and source of samples.

Sample Container: 50 mL, polypropylene, conical tubes.

Sample Test Kit: Call the laboratory to obtain sample collection kit and instructions prior to sample collection.

Shipping Requirements: Ship in an appropriate box or padded mailer. Package, mark and label properly to avoid sample loss during delivery.

Fee: \$ 60 per sample kit of 4. Fee waived for families of lead poisoned children.

Test Name: **Lead, Paint Chips**

Lab and Phone #: **Analytical Chemistry Laboratory** (617) 983-6654

Use of Test: To monitor paint as possible source of lead exposure.

Method of Analysis: Microwave digestion followed by flame atomic absorption spectroscopy.

Allowable Limits: Lead-based paints for interior application must contain less than 0.5% by weight lead.

Turnaround Time: 3 to 10 working days.

Sample Volume: 1.0 gram

Forms Required: Paint Sample Submission Form, complete with documentation of provider, occupant of dwelling, and source of samples. Call laboratory for copy of form.

Container: Submit in clean, zip-lock plastic bag.

Sample Collection: Call the laboratory for sampling instructions prior to collection.

Shipping Requirements: Use a padded mailer.

Fee: \$ 10 per sample. Fee waived for families of lead poisoned children.

Test Name: **Lead, Pottery**

Lab and Phone #: **Analytical Chemistry Laboratory** (617) 983-6654

Use of Test: To test for potential of lead toxicity from pottery or dinnerware used for food preparation or eating purposes. Items sent for analysis must be intact and not chipped, cracked or broken.

Method of Analysis: Acid extraction followed by flame atomic absorption spectroscopy.

Test Includes: Dinnerware, glassware, mugs, cups and other eating and drinking utensils.

Allowable Limits: All pottery, dinnerware and glassware must contain less than 2 ppm leachable lead under the Massachusetts Lead Law.

Turnaround Time: 5 to 10 working days

Forms Required: Miscellaneous Sample Submission Form with complete documentation of provider and manufacturer as well as a description of and source of the item. Call the laboratory for a copy of the form.

Shipping Requirements: Wrap all items well with bubble wrap or paper before shipping. Mark "Fragile,"

Hand Cancel" or Handle with Care" on the outside of the package. The laboratory is not responsible for broken or damaged items.

Fee: \$ 60 /sample. Fee waived for the families of lead poisoned children.

Test Name: **Lead, Soil**
Lab and Phone #: **Analytical Chemistry Laboratory (617) 983-6654**
Use of Test: To monitor soil as a possible source of lead toxicity.
Method of Analysis: Microwave digestion followed by flame atomic absorption spectroscopy.
Allowable Limit: EPA Guidelines, 400 mg/kg
Turnaround Time: 3 to 10 working days.
Sample Volume: One cup or more of a composite soil sample.
Forms Required: Soil Sample Submission Form complete with documentation of provider, occupant of dwelling and source of samples. Call the laboratory for a copy of the form.
Sample Container: Submit samples in individual clean, zip-lock plastic bags.
Sample Collection: Call laboratory for sampling instructions prior to collection.
Shipping Requirements: Ship to the laboratory in an appropriate sized durable box. Mark, label and secure the box properly to avoid sample loss during delivery.
Fee: \$ 10/sample. Fee waived for families of lead poisoned children.

Test Name: **Lead, Urine** (for research purposes only).
Lab and Phone #: **Childhood Lead Screening Laboratory (617) 983-6650**
Use of Test: To monitor lead excretion.
Method of Analysis: Acid extraction followed by graphite furnace atomic absorption spectroscopy.
Acceptable Range: 1 to 13 μ g/L
Turnaround Time: 10 working days.
Sample Volume: 100 mL
Sampling Instructions: Call laboratory for sampling instructions and container.
Forms Required: Childhood Lead Screening Sample Submission Form.
Sample Container: Trace metal free urine specimen collection container.
Sample Collection: First void sample or an aliquot of a 24-hour urine collection. Measure and record the volume on required laboratory form.
Shipping Requirements: Keep sample refrigerated before mailing. Sample must be submitted to the laboratory for preservation within 24 hours of collection. Secure container to avoid sample loss. Package and label outer packing properly to ensure safe delivery.
Comments: **Additional test recommended:** Blood Lead.

Test Name: **Lead, Water**
Lab and Phone: **Analytical Chemistry Laboratory (617) 983-6654**
Use of Test: To measure lead in drinking water as a possible source of exposure.
Method of Analysis: Acid extraction followed by graphite furnace atomic absorption spectroscopy.
Allowable Limits: 15 micrograms per liter (ug/L) or less.
Turnaround Time: 7 to 10 days
Sample Volume: Three 1000-mL compliance samples, collected over time, (standing, two minutes running and five minutes running).

Forms Required:	Drinking Water Submission Form containing documentation of provider, occupant, water source, and exact location of tap. Call the laboratory for a copy of the form.
Sample Test Kit:	EPA approved containers packaged for chain-of-custody supplied by laboratory.
Sample Collection:	See complete instructions in test kit for collecting compliance samples.
Shipping Requirements:	Secure covers to containers to prevent any leakage. Ship to laboratory in carton provided within 10 days of collection. Carton must have labels of orientation and handling to ensure safe delivery.
Fee:	\$ 40.00 per kit. Each kit includes 3 containers for collection of compliance samples. Shipping fee, if required is \$2.50. Testing fees are waived for families of lead poisoned children.

Test Name:	<u>Lead, Whole Blood, Capillary Fingerstick</u>
Lab and Phone #:	Childhood Lead Screening Laboratory (617) 983-6665
Use of Test:	Identification and monitoring of children with elevated lead body burden.
Method of Analysis:	Graphite furnace atomic absorption spectroscopy.
Acceptable Range:	Children 0 to 9 μ g/dL
Turnaround Time:	2 working days.
Sample and Volume:	200 μ L whole blood; collect with EDTA, heparin is also acceptable.
Sampling Instructions:	Call laboratory for sampling instructions.
Forms Required:	Childhood Lead Screening Sample Submission Form.
Sample Collection Kit:	Microcuvette capillary collection system, amber colored, coated with EDTA.
Shipping Requirements:	Call laboratory to order supplies.
	Keep samples refrigerated before mailing. Avoid exposing samples to extreme temperatures during shipping. Use double packaging system and an overpack for transporting clinical diagnostic specimens by courier. Use the triple packaging system when sending clinical blood samples by USPS. Do not mail samples in paper envelopes. Use biohazard stickers on primary receptacles and outer packings. Label outer packings "Diagnostic Specimen Enclosed" as required by USPS and CDC.
Comments:	See the Centers for Disease Control guidelines for the interpretation of Lead (Pb) and Zinc Protoporphyrin (ZnPP) blood levels at http://cdc.gov/nceh/lead/Publications

Test Name:	<u>Lead, Whole Blood, Venous Blood</u>
Lab and Phone #:	Childhood Lead Screening Laboratory (617) 983-6665
Use of Test:	Identification and monitoring of children with elevated lead body burden.
Method of Analysis:	Graphite furnace atomic absorption spectroscopy.
Acceptable Range:	Children 0 to 9 μ g/dL; Adults 0 to 40 ug/dL
Turnaround Time:	2 working days.
Sample and Volume:	2 mL of whole blood collected in EDTA, (lavender top tube). Although heparin, (green stopped tube) is acceptable, EDTA is the preferred anticoagulant .
Sampling Instructions:	Call the laboratory for sampling instructions.
Forms Required:	Childhood Lead Screening Sample Submission Form.
Sample Container:	2 mL (Pediatric), Vacutainer tube, plastic, lavender top (containing EDTA).

Shipping Requirements:	Keep samples refrigerated before mailing. Avoid exposing samples to extreme temperatures during shipping. Use double packaging system for transporting clinical diagnostic specimens by courier. Use triple packaging system when sending clinical blood samples by USPS. Use biohazard stickers on primary receptacles and outer packings. Label outer packings "Diagnostic Specimen Enclosed" as required by USPS and CDC.
Comments:	See the Centers for Disease Control guidelines for the interpretation of Lead and Zinc Protoporphyrin blood levels at (http://cdc.gov/nceh/lead/Publications)

Test Name:	<u>Legionella Culture</u>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	To confirm a diagnosis of Legionnaire's Disease in the acute phase of illness.
Test Includes:	Subculture identification, confirmation, and serogrouping as well as isolation and identification of <i>Legionella</i> spp. from lung tissue, pleural fluid, transtracheal aspirate, and lower respiratory secretions (sputum bronchial wash etc.).
Limitations:	Sputum, transtracheal aspirate and lung tissue have the highest yield. Pleural fluid has the lowest yield. Soluble antigen studies on all specimens are not offered.
Availability:	Monday through Friday.
Turnaround Time:	4 to 10 days.
Sample:	Lung tissue, pleural fluid, transtracheal aspirate, and lower respiratory secretions (sputum bronchial wash etc.).
Forms Required:	Legionella Requisition Form.
Sample Test Kit:	Legionella Transport Kit, available on request at (617) 983-6607 or (617) 983-6640.
Sample Collection:	Coolant provided by the user.
Shipping Requirements:	Collect pea-sized piece of tissue and 5 to 30 mL of secretions. Specimens should be held at 4-8° C and should not be allowed to dry out. Add a small amount of sterile distilled water to lung tissue if necessary. Do not use sterile saline for specimen collections as <i>Legionella</i> spp. are inhibited by saline.
Comments:	Additional tests recommended: <i>Legionella</i> Serology.

Test Name:	<u>Legionella Referred Culture</u>
	See <i>Legionella</i> Culture.

Test Name:	<u>Legionella Serology</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	To support a diagnosis of Legionnaires disease retrospectively during the convalescent phase of illness.
Test Includes:	Quantitative IFA testing for IgG antibody to <i>Legionella</i> .

Significant Result:	Seroconversion or a four-fold rise in titer or a single serum less than or equal to 256.
Limitations:	Varying background levels of antibody in the general population make it difficult to support a diagnosis based on a single serum titer.
Availability:	As requested.
Turnaround Time:	2 to 5 days upon receipt of convalescent serum.
Sample and Volume:	3 mL of serum, acute and convalescent.
Forms Required:	Virus Serology Requisition Form.
Sample Test Kit:	Virus Serology Kit. See instructions for sample collection in sample test kit.
Sample Collection:	Routine blood draw, no preservatives. Requisition must state date of collection and onset of illness. Collect acute during first week of illness and convalescent 3-6 weeks post-onset
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use the triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments:	Additional tests recommended: <i>Legionella</i> Culture.

Test Name: **Leishmaniasis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Leptospirosis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Listeria Isolation, Food**
Lab and Phone #: **Bacteriology Food Laboratory (617) 983-6610**
Use of Test: To support epidemiologic evidence implicating a food as a possible source of illness.
Special Instructions: Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The laboratory should be notified by phone prior to submission. If the sample is a commercial food or if the suspect agent is chemical, the laboratory investigation is handled by the SLI Environmental Chemistry Laboratory or the FDA.
Test Includes: Enrichment and culture of sample for *Listeria* species, Organoleptics.
Limitations: Foods will be examined for *Listeria* only if the clinical and epidemiologic information is compatible with *Listeria* foodborne disease.
Availability: Monday through Friday.
Turnaround Time: 3 to 12 days.
Sample and Volume: More than 200 grams of implicated food.
Forms Required: Sample Submission Forms are obtainable through the Food Microbiology Laboratory (617) 983-6610, MA Division of Food and Drugs, Food Protection Program (617) 983-6712, and the local Board of Health.

Sample Container:	Original sample container as submitted by inspector or other sterile leak proof container.
Sample Collection:	Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information.
Shipping Requirements:	Transport or ship samples on ice in appropriate packings.
Test Name:	<i>Listeria monocytogenes</i> Culture
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	Epidemiological studies.
Test Includes:	Confirmation of isolate. Additional studies (PFGE) may be performed.
Availability:	Monday through Friday.
Turnaround Time:	3 to 7 days.
Sample:	Pure, actively growing culture on agar slant.
Forms Required:	Bacteriology Requisition Form.
Shipping Requirements:	Use UN approved packagings. Pack, mark, label and ship as an infectious substance.

Test Name:	<u>Lyme Disease, Western Blot IgM and IgG</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	To confirm a diagnosis of Lyme disease as a follow-up positive to a screening assay.
Test Includes:	Separate confirmatory Western Blot tests for IgM and IgG antibody to <i>Borrelia burgdorferi</i> .
Significant Result:	IgM greater than or equal to 2 significant bands. IgG greater than or equal to 5 significant bands.
Limitations:	Western Blot testing is recommended only on patients who have positive EIA or IFA test results. Western Blot testing should not be performed as screening procedure for the general population. The predictive accuracy of a positive or negative Western Blot result depends on the likelihood of Lyme disease being present. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy. IgM serologic positivity should be considered only if specimen was obtained less than 30 days post disease onset.
Availability:	Weekly.
Turnaround Time:	2 to 7 days.
Sample and Volume:	3 mL of serum. See instructions in test kit.
Forms Required:	Lyme Serology Requisition Form. Call the Laboratory for copies of form.
Sample Test Kit:	Virus Serology Kit.
Sample Collection:	Routine blood draw, use no preservatives.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use the triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments:	Reactive screening results required for Immunoblot to be preformed. An IgG

blot is considered positive if five of the following ten bands are present: 18, 23 (OspC), 28, 30, 39, 41 (Flagellin), 45, 58, 66 and 93kDa. An IgM blot is considered positive if two of the following three bands are present: 23 (OspC), 39, and 41 (flagellin) kDa.

Test Name:	<u>Lymphocytic Choriomeningitis (LCM) Virus Culture and Serology</u>
Lab and Phone #:	Virus Isolation Laboratory (617) 983-6382
Special Instructions:	Virus Serology Laboratory (617) 983-6396 PLEASE CONTACT LABORATORY PRIOR TO SHIPPING SECIMENS. Samples are sent to CDC. This is a CDC referral test requiring at least 0.5 ml of cerebrospinal fluid and 3 mL of serum. The CDC will perform antibody testing on the serum and cerebrospinal fluid. Based on these results, CDC may elect to perform LCM culture testing or may determine that LCM culture testing is not warranted. Clinical information, including any known rodent exposure is required. Alternatively, LCM serology, requiring only serum, may be requested (see "CDC Serology - Viral/Rickettsial").
Test Includes:	LCM culture and antibody testing performed by the CDC at their discretion following antibody testing.
Turnaround Time:	Varies with referral.
Sample and Volume:	Minimum of 0.5 mL of cerebrospinal fluid with 3 mL of serum (required). Brain tissue may be acceptable following CDC consultation.
Forms Required:	Virus Isolation or Virus Serology Requisition Form and CDC Requisition Form.
Sample Test Kit:	Virus Serology Kit.
Sample Collection:	See instructions provided in test kit.
Shipping Requirements:	Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name:	<u>Malaria, Direct Smear</u>
Lab and Phone #:	Shipped to CDC with prior arrangement.
Use of Test:	Bacteriology Reference Laboratory (617) 983-6607
Limitations:	Diagnosis of malaria or speciation of an etiologic agent.
Turnaround Time:	Proper collection and staining.
Sample:	2 to 4 weeks.
Forms Required:	Thick and thin blood smears.
Sample Container:	CDC Requisition Form.
Shipping Requirements:	Provided by user.
	Ship in a UN approved package for Class 6.2 infectious substances. Pack, mark, label and ship as an infectious substance.

Test Name: **Malaria Serology**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Measles Antibody**
Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396
Use of Test: Confirmation of measles infection.
Test Includes: Quantitative IgG antibody complement fixation test for measles.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: Cannot distinguish between antibody produced in response to vaccination and antibody produced in response to wild strain measles infection.
Availability: Anticomplementary activity may interfere.
Turnaround Time: As requested.
Sample and Volume: 2 to 7 days upon receipt of convalescent serum.
3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute and convalescent serum. See instructions in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments: **Additional tests recommended:** Use measles HI and IgM antibody for early diagnosis on acute serum specimen. Parvovirus and Rubella antibody testing may be necessary for differential diagnosis.

Test Name: **Measles IgM Antibody**
Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396
Use of Test: Early diagnosis of measles infection.
Test Includes: Measles IgM Capture EIA.
Significant Result: Positive IgM indicates current or recent measles infection. Negative IgM-Positive Total Ab (see Measles HI test) indicates probable non-measles rash. Negative IgM-Negative Total Ab indicates probable non-measles rash or sample collected too early, convalescent specimen should be submitted to rule out measles infection.
Limitations: IgM may be negative if the specimen is collected prior to the appearance or close to onset of the rash. Cannot distinguish between antibody produced in response to vaccine versus wild strain measles.
Availability: As requested.
Turnaround Time: 1 to 3 days.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute serum collected 3 to 7 days after appearance of rash. See instructions in kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple

Comments: packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances. **Additional tests recommended:** Contact Epidemiology at (617) 983-6800 to report all suspect measles cases. Parvovirus and Rubella antibody testing may be necessary for differential diagnosis.

Test Name: **Measles Total Antibody (IgM and IgG)**
Lab and Phone #: **Virus Serology Laboratory (617) 983-6396**
Use of Test: Confirmation of measles infection.
Test Includes: Testing for total measles antibody by inhibition of hemagglutination.
Significant Result: Seroconversion or four-fold rise in titer.
Limitations: Cannot distinguish between antibody produced in response to vaccination and antibody produced in response to wild strain measles infection.
Availability: As requested.
Turnaround Time: 2 to 7 days.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute and possibly convalescent serum. See instructions in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments: **Additional tests recommended:** Use measles IgM antibody for early diagnosis on acute serum specimen. Epidemiology (617) 983-6800 should be contacted for all suspect measles cases. Parvovirus and Rubella antibody testing may be necessary for differential diagnosis.

Test Name: **Measles Virus Culture**
Lab and Phone #: **Virus Isolation Laboratory (617) 983-6382**
Limitations: Measles virus is rarely isolated from clinical specimens. IgM serology is the recommended test for measles diagnosis.
Availability: As requested.
Turnaround Time: 21 days for negative report. Positive reports are available in less time.
Sample: Throat and/or nasopharyngeal swab (combined specimens preferred), urine.
Forms Required: Virus Isolation Requisition Form.
Sample Test Kit: Provided by user.
Sample Collection: Call the laboratory for sample collection instructions.
Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the

Comments: container according to DOT and/or USPS regulations for infectious substances.
Additional tests recommended: IgM serology is the recommended test for measles diagnosis. Parvovirus and Rubella antibody testing may be necessary for differential diagnosis. Epidemiology (617) 983-6800 should be contacted for all suspect measles cases.
Note: Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: Mercury, Urine (for research purposes only).
Lab and Phone #: **Analytical Chemistry Laboratory** (617) 983-6653
Use of Test: To measure acute mercury exposure.
Method of Analysis: Extraction followed by flow injection atomic spectroscopy.
Normal Range: 5 ug/g creatinine
Toxic Concentration: >35 ug/grams creatinine
Turnaround Time: 10 working days.
Sample Volume: 100 mL
Sampling Instructions: Call laboratory for sampling instructions and container.
Forms Required: Proper documentation of provider, patient and sample source.
Container: Trace metal free urine specimen collection container.
Collection: First void sample or an aliquot of 24-hour collection. Measure and record the volume on the required laboratory form.
Shipping Requirements: Sample must be submitted to the laboratory for preservation within 24 hours of collection. Secure container to avoid sample loss. Package and label properly to ensure safe delivery.
Comments: All trace metal levels in urine are corrected for creatinine.

Test Name: Mucormycosis Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: Mumps Antibody
Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396
Use of Test: Serodiagnosis of recent infection with this agent
Test Includes: Quantitative IgG antibody complement fixation testing for mumps.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: May cause heterotypic antibody rise to parainfluenza type 2.
Availability: Anticomplementary activity may interfere.
Turnaround Time: As required.
Sample and Volume: 2 to 7 days upon receipt of convalescent serum.
Forms Required: 3 mL of serum.
Sample Test Kit: Virus Serology Requisition Form.
Sample Collection: Virus Serology Kit.
Shipping Requirements: Acute and convalescent serum. See instructions in test kit.
Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container “Clinical Specimen” as appropriate. If the sample contains a known

Comments:

pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Additional tests recommended: Mumps-IFA is the preferred diagnostic test. Epidemiology (617) 983-6800 should be contacted for all suspect mumps cases. Adenovirus and parainfluenza may cause similar symptoms. Testing for non-mumps, causes of parotid pain, or swelling should also be considered. This may include testing for coxsackie, echo, parainfluenza, influenza A, herpes simplex, herpes zoster virus and *s. aureus*.

Test Name: **Mumps Culture**

Lab and Phone #: Virus Isolation Laboratory (617) 983-6382

Availability: As requested.

Turnaround Time: 5 to 15 days.

Sample: Saliva, throat swab, urine, cerebrospinal fluid, and tissue.

Forms Required: Virus Isolation Requisition Form.

Sample Test Kit: Virus Isolation Kit.

Sample Collection: Call the laboratory for sample collection instructions.

Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments:

Additional Tests Recommended: Mumps serology testing is also available. Epidemiology (617) 983-6800 should be contacted for all suspect mumps cases.

Note: Culture for additional viruses may be performed at the discretion of the laboratory.

Test Name: **Mumps IgG IFA**

Lab and Phone #: Virus Serology Laboratory (617) 983-6396

Use of Test: Serodiagnosis of recent infection.

Significant Result: Seroconversion or four-fold increase in titer.

Availability: As requested.

Turnaround Time: 2 to 5 days upon receipt of convalescent serum.

Sample and Volume: 3 mL of serum.

Forms Required: Virus Serology Requisition Form.

Sample Test Kit: Virus Serology Kit.

Sample Collection: Acute and convalescent serum. See instructions in test kit.

Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments:

Additional tests recommended: Mumps IgM. Epidemiology (617) 983-6800 should be contacted for all suspect mumps cases. Adenovirus and parainfluenza

may cause similar symptoms. Testing for non-mumps causes of parotid pain or swelling should also be considered. This may include testing for coxsackie, echo, parainfluenza, influenza A, herpes simplex, herpes zoster virus and *s. aureus*.

Test Name:	<u>Mumps IgM and IgG EIA</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	Early diagnosis of mumps infection.
Test Includes:	Mumps IgM and IgG EIA performed at CDC.
Significant Result:	Positive IgM indicates probable current or recent mumps infection. Negative IgM and positive or negative IgG indicates probable non-mumps cause or possibility that the specimen was collected too early.
Limitations:	(1) 30% of primary mumps may be sub-clinical. (2) Mumps infection can occur without parotitis. (3) Parotid swelling may have other viral/bacterial causes (Coxsackie, Echo, Parainfluenza, Influenza A, Herpes Simplex and Zoster, and <i>S. aureus</i>). (4) Parotid pain or swelling may have a non-infectious cause.
Availability:	Sent per as needed.
Turnaround Time:	Unknown.
Sample and Volume:	3 mL of serum.
Forms Required:	Virus Serology or CDC Requisition Form.
Sample Test Kit:	Virus Serology Kit.
Sample Collection:	Acute serum collected 2 to 14 days post onset. Convalescent, if needed, 2 to 3 weeks later. See instructions in test kit.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments:	Additional tests recommended: Mumps culture. Epidemiology (617) 983-6800 should be contacted for all suspect mumps cases.

Test Name:	<u>Murine Typhus Antibody</u>
	See Rickettsia Antibody Panel.

Test Name:	<u>Mycobacteria spp. Stock Culture</u>
Lab and Phone#:	Mycobacteriology Laboratory (617) 983-6381
Use of test:	Cultures may be used for quality control, teaching, research or for reference purposes.
Special Instructions:	Please call the laboratory for instructions.
Test Includes:	Pure culture of most of the Mycobacteria isolated from clinical specimens.
Limitations:	Limited to organisms available.
Availability:	Monday through Friday.
Turnaround Time:	2 weeks.
Forms Required:	This non-routine request is not on the TB Laboratory Requisition Form.
Sample Test Kit:	TB Culture Kit.
Shipping Requirements:	If risk group 2,3 or 4 organism, ship as infectious substance using triple

packaging system. Pack, mark and label appropriately to meet USPS and DOT regulations.

Test Name:

Mycobacteriology CDC Identification

See CDC Culture Identification, Mycobacteriology.

Test Name:

Mycobacteriology, (MAC) Identification by Accuprobe

Lab and Phone #: **Mycobacteriology Laboratory (617) 983-6381**

Identification of *M. avium* complex isolates.

Use of test: Confirmation or identification of *M. avium* complex by Genprobe Accuprobe.

Test Includes: Availability: Tuesday through Friday.

Turnaround Time: 1 day for grown isolates and up to 1 month if isolation is necessary.

Sample and Volume: Positive AFB culture, either solid or liquid is acceptable.

Forms Required: TB Laboratory Requisition Form.

Sample Container: TB Culture Kit.

Shipping Requirements: Use double packaging system for Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate.

Test Name:

Mycobacteriology (MTD) *Mycobacterium Tuberculosis* Direct

Lab and Phone #: **Mycobacteriology Laboratory (617) 983-6381**

Use of Test:

To determine the in vitro diagnostic detection of *Mycobacterium tuberculosis* complex rRNA in acid-fast (AFB) smear positive concentrated sediments prepared from sputum, bronchial specimens or tracheal aspirates. Other types of specimens are tested by request on a research basis.

Special Instructions: Contact the laboratory before submitting specimen to arrange for testing. Patient specimens must be decontaminated within 24 hours after collection. Sediments must be analyzed within 72 hours after decontamination.

Limitations: Only for the detection of members of the *Mycobacterium tuberculosis* complex using sediments prepared following the NALC-NaOH and NaOH procedures recommended by CDC. MTD is specific for, but does not differentiate among, members of the *M. tuberculosis* complex. A negative test does not exclude the possibility of isolating an *Mycobacterium tuberculosis* complex organism from the specimen. MTD should always be performed in conjunction with mycobacterial culture. This test is for first time, smear positive patients that have not had a previous *Mycobacterium tuberculosis* complex infection.

Availability: Monday through Friday.

Turnaround Time: 24 to 48 hours.

Sample: Patient specimen or sediment of a sputum, bronchial specimen or tracheal aspirate. Other types of specimens are tested by request on a research basis.

Forms Required: TB Laboratory Requisition Form.

Sample Test Kit: TB Culture Kit.

Comments: Additional tests recommended: Mycobacteriology culture.

Shipping Requirements: Must use the triple packaging system when pathogens are known or suspected when shipping by U. S Mail or Courier Service. Label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name:	<u>Mycobacteriology (TB) Identification (Referred Culture)</u>
Lab and Phone #:	Mycobacteriology Laboratory (617) 983-6381
Use of Test:	To determine the species of mycobacteria.
Test Includes:	Confirmation or identification to the complex or species level by Genprobe Accuprobe, and/or biochemical testing.
Limitations:	Pure isolate. Mixed or contaminated cultures may take longer and identification may not be possible. Liquid cultures are acceptable.
Availability:	Tuesday through Friday.
Turnaround Time:	1 day to one month.
Sample:	Pure isolate.
Form Required:	TB Laboratory Requisition Form.
Sample Test Kit:	TB Culture Kit.
Shipping Requirements:	Use the double packaging system for delivery by a Courier Service. Use the triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If pathogens are known or suspected, use a triple packaging system when shipping by U. S Mail or Courier Service. Label and mark the outside of the container according to USPS and/or DOT regulations for infectious substances. A shipper's declaration is required for infectious substances.

Test Name:	<u>Mycobacteriology (TB) Smear</u>
Lab and Phone #:	Mycobacteriology Laboratory (617) 983-6381
Use of Test:	Presumptive diagnosis of mycobacterial disease; rapid identification of most infectious cases, e.g. those that are smear positive; to follow progress of tuberculosis patient on chemotherapy; to evaluate if patient may be discharged from hospital or return to gainful employment. The laboratory strongly recommends this test be done in conjunction with mycobacterial culture.
Test Includes:	Acid Fast Smear only.
Normal Range:	No AFB found.
Limitations:	Much less sensitive than culture for detecting mycobacteria.
Availability:	Monday through Friday.
Turnaround Time:	24 hours.
Sample and Volume:	Prepared slide or 1 to 3 mL of specimen.
Forms Required:	TB Laboratory Requisition Form.
Sample Test Kit:	TB Culture Kit.
Shipping Requirements:	Use the double packaging system for Courier Service. Use the triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. The triple packaging system must be used if pathogens are known or suspected when shipping by U. S Mail or Courier Service. Label and mark the outside of container according to USPS and/or DOT regulations for infectious substances. A shipper's declaration is required for the postal service.
Comments:	Additional tests recommended: Mycobacteria Culture.

Test Name: **Mycobacteriology (TB) Smear and Culture (AFB)**
Lab and Phone: **Mycobacteriology Laboratory (617) 983-6381**
Use of Test: Determine presence or absence of *mycobacteria*; if present identify the species using Genprobe Accuprobe or biochemical testing.

Test Includes: Acid Fast Smear and Culture.
Availability: Monday through Friday.
Turnaround Time: Smear 24 hours, culture 1 to 8 weeks.
Patient Preparation: Collect specimens prior to chemotherapy. Sterile preparation of site if applicable.

Sample and Volume:

•Body Fluids (containing blood)

Volume: 10 mL
Container: Blood collection tube.
TB Culture Kit

•Body Fluids (not containing blood)

Volume: 10 to 15 mL
Container: TB Culture Kit

•Blood

Volume: 10 mL
Container: Blood collection tube.
TB Culture Kit

•Bone Marrow

Volume: 1 to 10 mL
Container: Blood collection tube.
TB Culture Kit

•Cerebrospinal Fluid

Volume: \geq 2 mL
Limitations: Cerebrospinal fluid submitted in CSF collection tubes with attached caps usually leak in transport. Transfer specimen to container provided in TB Culture Kit.

•Gastric Lavage

Volume: \geq 5 to 10 mL
Container: TB Culture Kit
Limitations: Specimens that have not been neutralized, (buffered) are unacceptable.
Special Instructions: Collect fasting specimen soon after patient awakens in order to obtain sputum swallowed during sleep. Collect 3 specimens on different days. Neutralize immediately, submit on day of collection and indicate on requisition form that the specimen has been neutralized.

•Skin Lesion Material

Volume: 1 cubic centimeter
Container: TB Culture Kit.
Limitations: Do not wrap in gauze. Do not freeze. 1 to 2 mL of sterile saline may be used to keep tissue moist. Swabs are not recommended. Negative results obtained from specimens submitted on swabs are not reliable.

•Sputum

Volume: 5 to 10 mL
Container: TB Culture Kit.

Limitations: 24-hour pooled specimens and saliva are unacceptable specimens.

Special Instructions: Collect a series of 3 to 5 specimens collected on different days over a 7 day period. Submit on day of collection.

•Stool

Volume: ≥ 1 g

Container: TB Culture Kit. Call for prior approval.

•Tissue Biopsy

Volume: 1 cubic centimeter

Container: TB Culture Kit.

Limitation: Do not wrap in gauze. Do not freeze. 1 to 2 mL of sterile saline may be used to keep tissue moist. Swabs are not recommended. Negative results obtained from specimens submitted on swabs are not reliable.

•Urine

Volume: 20 mL

Container: TB Culture Kit.

Limitations: 24-hour pooled specimens are unacceptable.

Special Instructions: Collect a series of 3 to 5 specimens collected on different days. Collect first morning clear voided midstream specimen. Submit sample to the laboratory on the day of collection.

Form Required:

TB Laboratory Requisition Form.

Shipping Requirements:

Apply basic double packaging system for Courier Service. Apply a biohazard label and mark the outer container "Clinical Specimen". Use the triple packaging system when shipping by U. S Mail. Label and mark the outside of the container according to USPS and/or DOT. Samples from patients with known TB should be packaged and shipped as infectious substances. A shipper's declaration is required for the postal service. Transport samples to the laboratory as soon as possible. Refrigerate if a delay in submitting is anticipated.

Comments:

Drug susceptibility testing is performed on all *M. tuberculosis* complex isolates.

Test Name:

Mycobacteriology (TB) Susceptibility

Lab and Phone #:

Mycobacteriology Laboratory (617) 983-6381

Use of Test:

To determine the in vitro susceptibility of mycobacteria to the above listed antimicrobial agents.

Test Includes:

Proportion method of testing mycobacterial isolates against Streptomycin, Isoniazid, Ethambutol, Rifampin, Ethionamide, Capreomycin, Cycloserine, Ciprofloxacin and Kanamycin.

Normal Range:

Pattern of susceptibility varies based on isolate.

Limitations:

Pure isolate, only done on pathogens.

Availability:

Monday through Friday.

Turnaround Time:

Primary specimens usually 7-8 weeks. Referred cultures usually 3 to 4 weeks.

Sample:

Primary specimen or mycobacterial isolate.

Forms Required:

TB Laboratory Requisition Form.

Sample Test Kit:

TB Culture Kit.

Shipping Requirements:

Use basic double packaging system for Courier Service. Use the triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical

Specimen" as appropriate. Samples from patients with known TB should be packaged and shipped as infectious substances. A shipper's declaration is required for the postal service. Transport samples to the laboratory as soon as possible.

Test Name: Mycobacteriology (TB) Susceptibility, Rapid
Lab and Phone #: Mycobacteriology Laboratory (617) 983-6381
Use of test: To determine the in vitro susceptibility of *M. tuberculosis* complex organisms to the first line drugs listed below.
Test Includes: Rapid radiometric susceptibility tests for TB using Bactec for Streptomycin (S), Isoniazid (I) [two concentrations], Ethambutol (E), Rifampin (R) and Pyrazinamide (PZA). The results are available 7 to 12 days after inoculation.
Normal Range: *M. tuberculosis* complex organisms susceptible to the above antimicrobial agents.
Limitations: Pure isolate, only done on *M. tuberculosis* complex organisms.
Availability: Test is set up on Friday. Send positive cultures as early in the week as possible.
Turnaround Time: One to three weeks.
Sample: *M. tuberculosis* complex isolate.
Forms Required: TB Laboratory Requisition Form.
Sample Test Kit: TB Culture Kit.
Shipping Requirements: Must use the triple packaging system if pathogens are known or suspected when shipping by U. S Mail or Courier Service. Label and mark the outside of container according to USPS and/or DOT regulations for infectious substances. A shipper's declaration is required for the postal service.

Test Name: *Mycoplasma pneumoniae* Antibody
Lab and Phone #: Virus Serology Laboratory (617) 983-6396
Use of Test: Serodiagnosis of recent or current infection with this agent.
Test Includes: Quantitative IgG antibody CF testing for *Mycoplasma pneumoniae*.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: Anticomplementary activity may interfere.
Availability: As requested.
Turnaround Time: 2 to 7 days upon receipt of convalescent serum.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute and convalescent serum. See instructions in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: *Neisseria gonorrhoeae*
See Gonorrhea Culture.

Test Name:	<u>Neisseria gonorrhoeae Antimicrobial Susceptibility</u>
Use of Test:	See Gonorrhea Culture.
Lab and Phone #:	<u>Neisseria meningitidis Culture</u>
Test Includes:	To serogroup isolate for use in treatment selection and/or epidemiological studies.
Limitations:	Bacteriology Reference Laboratory (617) 983-6607
Availability:	Serogrouping of <i>Neisseria meningitidis</i> .
Turnaround Time:	Testing performed only on organisms isolated from normally sterile sites unless prior consultation is arranged.
Sample:	Monday through Friday.
Forms Required:	1 to 2 days.
Shipping Requirements:	Pure young culture on agar slant.
Comments:	Bacteriology Requisition Form.
	Use triple packaging system. If known pathogen, pack, mark, label and ship as an infectious substance. Mark "DO NOT REFRIGERATE" on outside container.
	Additional tests recommended: Prior correct identification of <i>Neisseria meningitidis</i> is required.

Test Name:	<u>Nocardia (Culture)</u>
Lab and Phone #:	<u>Mycobacteriology Laboratory</u> (617) 983-6381
Use of test:	Presumptive identification of Nocardia and Rhodococcus to the genus level.
Test Includes:	Presumptive Identification of Nocardia and Rhodococcus to the genus level.
Normal Range:	Negative.
Limitations:	Pure isolate.
Availability:	Monday to Friday.
Turnaround Time:	One to three weeks.
Sample:	Positive isolate.
Forms Required:	TB Laboratory Requisition Form.
Sample Test Kit:	TB Culture Kit.
Turnaround Time:	One to three weeks.
Shipping Requirements:	Basic double packaging system for U. S Mail or Courier Service. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate.

Test Name:	<u>Nocardiosis Serology</u>
	See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name:	<u>Paracoccidioidomycosis Serology</u>
	See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name:	<u>Paragonimiasis Serology</u>
	See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name: Parainfluenza 1, 2, 3 Antibody
Lab and Phone #: Virus Serology Laboratory (617) 983-6396
Use of Test: Serodiagnosis of recent or current infection with this agent
Test Includes: Quantitative IgG antibody complement fixation (CF) testing for each of these agents.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: Infection with one serotype may elicit a significant titer change to both the homologous agent and another Parainfluenza serotype. Mumps infections may also result in a heterotypic rise in antibodies to parainfluenza Type 2.
Availability: Anticomplementary activity may interfere.
Turnaround Time: As required.
Sample and Volume: 2 to 7 days upon receipt of convalescent serum.
Forms Required: 3 mL of serum.
Sample Test Kit: Virus Serology Requisition Form.
Sample Collection: Virus Serology Kit.
Shipping Requirements: Acute and convalescent serum. See instructions in test kit.
Comments: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Additional tests recommended: Respiratory Virus Culture or Respiratory Virus Antibody Panel.

Test Name: Parainfluenza Virus Culture
See Influenza Virus Culture.

Test Name: Parasitic Serology (except for Toxoplasmosis)
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: Parvovirus B19 IgM and IgG Antibody
Lab and Phone #: Virus Serology Laboratory (617) 983-6396
Use of Test: Serodiagnosis of a recent or prior infection with this agent. In the absence of symptoms and when the IgM results is negative, the IgG test results can be used as an indicator of immunity.
Test Includes: Separate qualitative EIA testing for Parvovirus B19 IgM & IgG antibodies.
Significant Result: Presence of IgM indicates recent or current infection. IgM absent/IgG present suggests prior exposure.
Availability: As requested.
Turnaround Time: 3 to 7 days.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute phase serum specimen or convalescent for "immunity status". See instructions for sample collection in test kit.

Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: All suspect measles and rubella cases are routinely tested for parvovirus B19 IgM and IgG Antibody.

Test Name: Pertussis Culture
See *Bordetella pertussis* and other *Bordetella spp.* Culture.

Test Name: Pesticides and Industrial Chemicals in Food
Lab and Phone #: Analytical Chemistry Laboratory (617) 983-6653
Comments: Call the laboratory for specific sampling instructions. Testing will be evaluated on a case by case basis.

Test Name: PFGE
See Bacterial Typing and Pulsed Field Gel Electrophoresis.

Test Name: Plague Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: Plesiomonas shigelloides
See Enteric Pathogens, Referred Culture.

Test Name: Pneumonia
See Referred Bacterial Culture for Identification.

Test Name: Pneumonia, Atypical
See Mycoplasma pneumoniae Antibody; Respiratory Virus Antibody Panel; Psittacosis, and Q Fever Antibody.

Test Name: Poliovirus Culture
See Enterovirus Culture.

Test Name: Polychlorinated biphenyls (PCB), Serum (for research purposes only)
Lab and Phone #: Analytical Chemistry Laboratory (617) 983-6653
Use of Test: PCB exposure assessment.
Test Includes: Aroclor and specific congener analysis.

Turnaround Time: 30 working days.
Sample Volume: 5 mL of serum.
Container: Red topped vacutainer, no anticoagulant, no serum separator tubes.
Collection: Call laboratory for specific sample collection, storage and transport instructions.

Test Name: **Psittacosis**
See *Chlamydia psittaci* Antibody.

Test Name: **Pulsed Field Gel Electrophoresis (PFGE)**
See Bacterial Typing, and PFGE.

Test Name: **Q Fever Antibody**
Lab and Phone #: **Virus Serology Laboratory (617) 983-6396**
Use of Test: Serodiagnosis of recent or current infection with this agent
Test Includes: Quantitative IgG antibody CF testing for *Coxiella burnetii*.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: Anticomplementary activity may interfere.
Availability: As requested.
Turnaround Time: 2 to 7 days upon receipt of convalescent serum.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute and convalescent serum. See instructions in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **Rabies Test, Antigen Detection, Human**
Lab and Phone #: **Sample sent to CDC.**
Special Instructions: **Virus Isolation Laboratory (617) 983-6382**
Sample: **Contact Epidemiology at (617) 983-6800 before submitting sample.**
Forms Required: Sample of brain or sample of a neck skin punch sent to the laboratory will be shipped to CDC.
Sample Collection: Virus Serology Requisition Form or CDC Requisition Form.
Sample Test Kit: Collect a portion of brain or skin punch from the back of the neck.
Shipping Requirements: Provided by user.
Patient Preparation: Transport to the laboratory within 24 hours at refrigerated temperatures. Use triple packaging system for transporting by Courier Service in accordance with CDC and DOT regulations. Apply a biohazard label and mark the outer container as appropriate.
Exposed patient should consult with physician and epidemiologist. It may be necessary to start Rabies post-exposure treatment immediately.

Comments:	Persons suspecting an exposure should notify their doctor and contact the Epidemiology Department at (617) 983-6800.
Test Name:	<u>Rabies Test, Antigen Detection, Non-Human</u>
Lab and Phone #:	Rabies Laboratory (617) 983-6385
Use of Test:	Identification of Rabies in animals.
Special Instructions:	Persons suspecting an exposure should notify their doctor and contact the Epidemiology Department at (617) 983-6800. With the exception of bats, only the head of the animal will be accepted. For bats, submit the whole body.
Limitations:	The different regions of the brain must be discernible to perform a satisfactory test. It is important that the sample be intact and not mutilated.
Availability:	Monday through Friday. Weekends and holidays when approved by epidemiologist.
Turnaround Time:	Same day on specimens received before 1:00 pm Monday through Friday. Next working day for specimens received after this time. Results of weekend testing will be reported by phone.
Sample:	Head or brain of animal. With the exception of bats, the whole body will not be accepted.
Sample Container:	Provided by user.
Forms Required:	Rabies Examination Requisition Form. Call the laboratory for a form.
Sample Test Kit:	Provided by user.
Sample Collection:	Animal heads (or brains) must be fresh and not crushed or mutilated.
Shipping Requirements:	Transport to the laboratory within 24 hours at refrigerated temperatures. Use triple packaging system for transporting by Courier Service in accordance with CDC regulations. Apply a biohazard label and mark the outer container "Clinical Diagnostic Specimen" as appropriate
Patient Preparation:	Exposed patient should consult with physician and epidemiologist. It may be necessary to start Rabies post-exposure treatment immediately.

Test Name:	<u>Referred Bacterial Culture for Identification</u>
	Non-Enteric, Public Health Panel
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	Definitive identification of bacteria of public health significance (see Limitations listed below).
Test Includes:	Identification of bacteria of public health significance. Enteric pathogens not included (See Enteric Pathogens, Referred Culture).
Limitations:	Panel includes the following organisms: <i>Bacillus anthracis</i> , <i>Bordetella</i> spp., <i>Brucella</i> spp., <i>Corynebacterium diphtheriae</i> , <i>Francisella tularensis</i> , <i>Haemophilus influenzae</i> , <i>Listeria monocytogenes</i> , <i>Neisseria gonorrhoeae</i> , <i>Neisseria meningitidis</i> and <i>Streptococcus pneumoniae</i> .
Availability:	Monday to Friday.
Turnaround Time:	2 days to 2 weeks.
Sample:	Pure culture on agar slant.
Forms Required:	Bacteriology Requisition Form.
Shipping Requirements:	Ship at room temperature in UN approved packagings. Package, mark, label

and ship as an infectious substance. See section on packaging and shipping specimens.

Comments: **Additional tests recommended:** Serogrouping/Serotyping of bacteria for use in epidemiological studies. Bacterial typing (PFGE), if involved in an outbreak.

Test Name: **Referred Culture (Bacterial) Serotyping (Non-enteric)**
(*N. meningitidis* *H. influenzae*, *L. pneumophila*, etc.)
Lab and Phone #: **Bacteriology Reference Laboratory** (617) 983-6607
Use of Test: To serotype or serogroup common pathogens for use in treatment selection and/or epidemiological studies.
Test Includes: Serogrouping of *Neisseria meningitidis*, *Legionella pneumophila*, and beta hemolytic *Streptococcus* spp.; serotyping of *Haemophilus influenzae*.
Limitations: Only done on organisms listed above.
Availability: Monday through Friday.
Turnaround Time: 1 to 3 days.
Sample: Pure culture on agar slant.
Forms Required: Bacteriology Requisition Form.
Shipping Requirements: Ship in UN approved packagings. Package, mark, label and ship sample as an infectious substance. If isolate is *N. meningitidis*, print "DO NOT REFRIGERATE" on outside of outer packing. See section on packaging and shipping specimens.
Comments: **Additional tests recommended:** Prior correct identification of *Neisseria meningitidis* and *Haemophilus influenzae* is required.

Test Name: **Referred Culture, Definitive Identification, Enteric Pathogens**
See Enteric Pathogens, Referred Culture.

Test Name: **Referred Culture, Definitive Identification, Mycobacteria**
See Mycobacteriology (TB) Identification (Referred Culture).

Test Name: **Referred Culture, Legionella**
See *Legionella* Culture.

Test Name: **Respiratory Syncytial Virus Antibody**
See RSV Antibody.

Test Name: **Respiratory Viruses Antibody Panel**
Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396
Use of Test: Serodiagnosis of recent or current infection with this agent
Test Includes: Quantitative IgG antibody complement fixation testing for influenza A and B, parainfluenza types 1-3, adenovirus, Mycoplasma pneumoniae, and respiratory

Significant Result: syncytial virus.
Limitations: Seroconversion or four-fold increase in titer.
Availability: Anticomplementary activity may interfere.
Turnaround Time: As required.
Sample and Volume: 2 to 7 days upon receipt of convalescent serum.
Forms Required: 3 mL of serum.
Sample Test Kit: Virus Serology Requisition Form.
Sample Collection: Virus Serology Kit.
Shipping Requirements: Acute and convalescent serum. See instructions in test kit.
Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **Rickettsia Antibody Panel**
Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396
Use of Test: Serodiagnosis of an infection with one of these agents.
Test Includes: Quantitative total antibody IFA testing for Rocky Mountain spotted fever and Murine typhus.
Significant Result: Four-fold titer change with convalescent titer \geq 1:128; single serum titer of 1:256 or greater.
Limitations: Some cross-reactivity between these two agents occurs in the lower dilutions.
Availability: As required.
Turnaround Time: 2 to 7 days.
Sample and Volume: 3 mL of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Collection: Usually acute and convalescent sera for diagnostic testing. See instructions in kit
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **RPR, (Rapid Plasma Reagins Card Test), Non-treponemal Syphilis Serology Test**
Lab and Phone #: **Bacteriology Laboratory** (617) 983-6600
Use of Test: Screening test for syphilis: The RPR test measures IgM and IgG antibodies to lipoidal material released from damaged host cells as well as to lipoproteinlike material, and possibly cardiolipin released from the treponemes. These antibodies are produced not only as a consequence to treponemal disease, but also in response to non-treponemal diseases in which tissue damage occurs. This test is also used to determine quantitative levels of non-treponemal antibodies to syphilis and to follow patients with syphilis who have been treated.

Test Includes:

QUALITATIVE SCREENING TESTING IS AVAILABLE ONLY ON SPECIMENS FROM ASSIGNED CLINICS: Assigned clinics are specific sites selected to monitor disease prevalence throughout the Commonwealth.

Qualitative and Quantitative testing on specimens submitted:

- For confirmation of reactive results obtained with non-treponemal screening tests
- For antibody testing follow-ups
- For assessment of treatment efficacy
- For assessment of patients with symptomatology consistent with infectious syphilis (primary, secondary, or early latent stages)

Normal Range:

Non- Reactive.

Limitations:

Prozone reactions occasionally occur in the screening tests, which may result in false negative results. They occur when there is complete or partial inhibition of reactivity with undiluted serum. **The RPR test cannot be used with spinal fluids.** The RPR may be reactive in persons from areas where yaws, pinta or non-venereal syphilis is endemic. Biologic False Positive reactions occur occasionally in specimens from persons who abuse drugs, have diseases such as lupus erythematosus, or have recently been vaccinated. Persons treated during latent or late stages may remain serofast. The test is not specific for syphilis.

Availability:

Monday through Friday.

Turnaround Time:

1 to 5 Days.

Sample and Volume:

Serum (\geq 3 mL) or whole blood (5 to 10 mL) collected in a red top or Serum Separator Tube (SST). Serum is preferable to whole blood. Use 13mm x 100mm or 16mm x 100mm tubes for collection. Allow blood to clot at least 30 minutes. Separate serum if centrifuge is available.

Forms Required:

Syphilis Serology Test Request Form SS-1 (09/00).

Sample Test Kit:

Syphilis Serology Single Kit (holds one tube) or Syphilis Serology Multiple Kit (holds up to 9 tubes). These kits may be ordered by calling (617) 983-6640.

Sample Collection:

Venipuncture, collect 5 to 10 mL in red top tube or SST. Use 13mm x 100mm or 16mm x 100mm tubes for collection. Allow blood to clot at least 30 minutes. Separate serum if centrifuge is available.

Shipping Requirements:

Serum may be shipped at room temperature, cold or frozen. Whole blood must be maintained at a temperature between 2°C and 27°C. Use double packaging system for couriers or triple packaging system for USPS.

Test Name:**RSV Antibody****Lab and Phone #:**

Virus Serology Laboratory (617) 983-6396

Use of Test:

Serodiagnosis of recent or current infection with this agent

Test Includes:

Quantitative complement fixation testing for IgG antibody to respiratory syncytial virus Quantitative IgG antibody CF testing for CMV.

Significant Result:

Seroconversion or four-fold increase in titer.

Availability:

Per as needed.

Turnaround Time:

2 to 7 days upon receipt of convalescent serum.

Sample and Volume:

3 mL of serum.

Forms Required:

Virus Serology Requisition Form.

Sample Test Kit:

Virus Serology Kit.

Sample Collection: Acute and convalescent serum. See instructions for collecting sample in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: **Additional tests recommended:** Respiratory Virus Culture.

Test Name: **Rubella Antibody**
Lab and Phone #: **Virus Serology Laboratory (617) 983-6396**
Use of Test: Confirmation of rubella infection.
Test Includes: Total rubella antibody testing by latex agglutination.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: Cannot distinguish between antibody produced in response to vaccination and antibody produced in response to wild strain rubella infection.
Availability: As required.
Turnaround Time: 1 to 3 days.
Sample and Volume: 3 mL of serum, no additives.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology Kit.
Sample Collection: Acute and possibly convalescent serum. See instructions in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: **Additional tests recommended:** Use rubella IgM antibody for early diagnosis on acute serum specimen. Epidemiology (617) 983-6800 should be contacted for all suspect rubella cases. Parvovirus and measles antibody testing may be necessary for differential diagnosis.

Test Name: **Rubella IgM Antibody**
Lab and Phone #: **Virus Serology Laboratory (617) 983-6396**
Use of Test: Confirmation of rubella infection.
Test Includes: Rubella IgM Solid Phase Immunosorbent Hemadsorption Assay.
Significant Result: Seroconversion or four-fold increase in titer.
Limitations: Cannot distinguish between antibody produced in response to vaccination and antibody produced in response to wild strain rubella infection.
Availability: As required.
Turnaround Time: 2 to 7 days.
Sample and Volume: 3 ml of serum.
Forms Required: Virus Serology Requisition Form.
Sample Test Kit: Virus Serology.
Sample Collection: Acute and possibly convalescent serum. See instructions in test kit.
Shipping Requirements: Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer

container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Comments: **Additional tests recommended:** Use rubella latex agglutination assay and IgM antibody for early diagnosis on acute serum specimens. Epidemiology (617) 983-6800 should be contacted for all suspect rubella cases. Parvovirus and measles antibody testing may be necessary for differential diagnosis.

Test Name: **Rubella Virus Isolation**
(Performed at Georgia State University)
Virus Isolation Laboratory (617) 983-6382
Isolation of Rubella virus in cell culture.
Rubella virus is rarely isolated from clinical specimens. Serology is recommended.
As requested.
Turnaround Time: Approximately one month.
Sample: Nasal wash (nasopharyngeal aspirate), nose/throat swabs, and urine.
Forms Required: Virus Isolation Requisition Form.
Sample Test Kit: Virus Isolation Kit.
Sample Collection: Call the Laboratory for instructions.
Shipping Requirements: Transport to the laboratory within 24 hours at refrigerator temperature. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.
Comments: **Additional tests recommended:** IgM serology is the recommended test for evidence of Rubella virus infection.
Note: Culture for additional viruses may be performed at the discretion of the laboratory. Epidemiology (617) 983-6800 should be contacted for all suspect rubella cases.

Test Name: **Rubeola**
See Measles Listings.

Test Name: **Salmonella Culture, Food**
See Salmonella Isolation, Food.

Test Name: **Salmonella Isolation, Food**
Lab and Phone #: **Bacteriology Food Laboratory (617) 983-6610**
Use of Test: To support epidemiologic evidence implicating a food as a possible source of illness.
Special Instructions: Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The laboratory should be notified by phone prior to submission. If the sample is a

commercial food or if the suspect agent is chemical, the laboratory investigation is handled by the SLI Environmental Chemistry Laboratory or the FDA.

Test Includes: Enrichment and culture of sample and serotyping on positive cultures, organoleptics.

Limitations: Foods will be examined for *Salmonella* only if the clinical and epidemiologic information is compatible with *Salmonella* foodborne disease.

Availability: Monday through Friday.

Turnaround Time: 4 to 7 days.

Specimen and Volume: More than 200 grams of implicated food

Forms Required: Sample Submission Forms are obtainable through the Food Microbiology Lab at (617) 983-6610, MA Division of Food and Drugs, Food Protection Program at (617) 983-6712, and the local Board of Health.

Sample Container: Original sample container as submitted by inspector or other sterile leak proof container

Sample Collection: Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information.

Shipping Requirements: Transport or ship samples on ice in appropriate packagings.

Comments: **Additional tests recommended:** Enteric Pathogens, Routine Culture.

Test Name: **Salmonellosis**
See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: **Schistosomiasis Serology**
See CDC Serology–Bacterial/Fungal/Protozoal

Test Name: **Serotyping Enteric Pathogens (*Salmonella*, *Shigella*, *Vibrio cholerae*, *E. coli* O157:H7)**
See Enteric Pathogens, Referred Culture.

Test Name: **Serotyping *Streptococcus pneumoniae*, *Streptococcus pyogenes* (M and T Typing)**
Lab and Phone #: **Bacteriology Reference Laboratory** (617) 983-6607
Use of Test: To determine serotype of *S. pneumoniae* in patients who received the pneumococcal vaccine or have multiple isolates (different infections); for epidemiological purposes in possible outbreaks; for treatment purposes and surveillance.

Test Includes: Confirmation of *S. pneumoniae*. Samples are shipped to the CDC for serotyping

Limitations: Reason for request must meet criteria above. Prior consultation with CDC may be required. *S. pyogenes* for M and T typing must have been isolated from normally sterile body fluids unless specific arrangements have been made with CDC Streptococcus Laboratory. Consult with Bacteriology at (617) 983-6607

Availability:	for CDC referral.
Turnaround Time:	Monday through Friday.
Sample:	3 weeks to several months.
Forms Required:	Pure culture on an agar slant.
Shipping Requirements:	Bacteriology Requisition or CDC Submission Form.
Shipping Requirements:	Use triple packaging system. Follow USPS and DOT regulations.
Test Name:	<u>Shiga Toxin-Producing <i>E. coli</i> (STEC)</u> See Shiga Toxin (Verotoxin) Assay.
Test Name:	<u>Shiga Toxin (Verotoxin) Assay</u>
Lab and Phone #:	Bacteriology Laboratory (617) 983-6600
Use of Test:	Confirm presence of Shiga toxin. Isolate Shiga-toxin producing organism(s) for subsequent identification.
Test Includes:	Test for Shiga toxin(s) by commercial in-vitro microwell Enzyme Immunoassay. Isolation of Shiga-toxin producing organism from mixed positive specimens for subsequent identification. Confirmation of suspected Shiga toxin-producing <i>E. coli</i> (STEC) or other suspected Shiga toxin producing organism and subsequent serotyping if applicable.
Normal Range:	Negative.
Limitations:	Mixed cultures and stool specimens must be submitted in a timely manner. Shiga toxin-producing organisms are usually present in far fewer numbers than normal background organisms and are easily overgrown by them. Isolation can be problematic when mixed cultures or stools are not submitted as soon as possible. Refrigeration helps retard overgrowth by background organisms.
Availability:	Once per week.
Turnaround Time:	2 to 7 days for confirmation of mixed culture and/or stool specimen. Successful isolation of the Shiga toxin-producing organism can take a few days longer. Final confirmation and serotyping are performed by the Centers of Disease Control (CDC), Atlanta, results of which are often not available for a month or more after submission to CDC.
Sample:	Pure subculture is preferable. Broth culture on ice and/or fresh stool on ice are also acceptable.
Forms Required:	Bacteriology Requisition Form obtained by calling (617) 983-6600 or Enteric Requisition Form, EC-1, included in the Enteric (stool collection/transport) Kit provided by the SLI.
Sample Container:	Screw-capped tube for cultures. A sterile stool collection container or enteric collection/transport medium for fresh stool provided by the SLI.
Sample Collection:	Collect stool specimen either in a sterile collection jar (ship on ice), or in the enteric kit (collection/transport medium) provided by the SLI. Kits may be ordered by calling (617) 983-6640.
Shipping Requirements:	Ship pure cultures or stools in Enteric collection/transport medium at room temperature. Ship mixed cultures or fresh stools with packaged refrigerant. Freezing is not recommended. Ship all submissions suspected to be Shiga toxin positive as infectious substances. Ship at ambient temperatures

using UN approved packagings. Mark and label the outer packaging as an infectious substance. See section on packaging and shipping specimens.

Test Name:	<u>Shigella Culture, Food</u> See <i>Shigella</i> Isolation, Food.
Test Name:	<u>Shigella Isolation, Food</u>
Lab and Phone #:	Bacteriology Food Laboratory (617) 983-6610
Use of Test:	To support epidemiologic evidence implicating a food as a possible source of illness
Special Instructions:	Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The lab should be notified by phone prior to submission. If the sample is a commercial food or if the suspect agent is chemical, the laboratory investigation is handled by the Environmental Chemistry Laboratory or the FDA.
Test Includes:	Enrichment and culture of sample and serotyping on positive cultures, Organoleptics.
Limitations:	Foods will be examined for <i>Shigella</i> only if the clinical and epidemiologic information is compatible with <i>Shigella</i> foodborne disease.
Availability:	Monday through Friday.
Turnaround Time:	3 to 7 days.
Sample and Volume:	More than 200 grams of implicated food.
Forms Required:	Sample Submission Forms are obtainable through the Food Microbiology Lab at (617) 983-6610, MA Division of Food and Drugs at (617) 983-6712, and the local Board of Health.
Sample Container:	Original sample container as submitted by inspector or other sterile leak proof container.
Sample Collection:	Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information.
Shipping Requirements:	Transport or ship samples on ice in appropriate packagings.
Comments:	Additional tests recommended: Enteric Pathogens, Routine Culture.

Test Name:	<u>Shigellosis</u>
	See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name:	<u>Sporotrichosis Serology</u>
	See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name:	<u>Staphylococcus aureus Culture, Food</u>
	See <i>Staphylococcus aureus</i> Plate Count, Food.

Test Name:	<u>Staphylococcus aureus, Culture, Stool</u>
	See Enteric Pathogens, Routine Culture
	Note: Only available through local Health Departments in Massachusetts.
	Limited to outbreak situations wherein <i>S. aureus</i> has been isolated and quantified in significant numbers from related food samples.
Test Name:	<u>Staphylococcus aureus Plate Count, Food</u>
Lab and Phone #:	Bacteriology Food Laboratory (617) 983-6610
Use of Test:	To support epidemiologic evidence implicating food as a source of illness.
Special Instructions:	Food samples must be submitted through local or state public health agencies and implicated in an outbreak (1 or more ill consumers). The laboratory should be notified by phone prior to submission. If the sample is a commercial food or if the suspect agent is chemical, the laboratory investigation is handled by the Environmental Chemistry Laboratory at the SLI or by the FDA.
Test Includes:	Culture of sample (Baird-parker Agar plate counts), organoleptics.
Limitations:	Foods will be examined for <i>S. aureus</i> only if the clinical and epidemiologic information is compatible with <i>S. aureus</i> foodborne disease.
Contraindications:	Food samples are examined from single or multiple cases of illness.
Availability:	Monday through Friday.
Turnaround Time:	2 to 4 days.
Sample and Volume:	200 grams of implicated food.
Forms Required:	Sample Submission Forms are obtainable through the Food Microbiology Laboratory at (617) 983-6610, MA Division of Food and Drugs, Food Protection Program at (617) 983-6712, and local Board of Health.
Sample Container:	Original sample container as submitted by inspector or other sterile leak proof container.
Sample Collection:	Collect food aseptically and place in sterile whirlpack bags or other sterile, leak proof container. Label with source (name of establishment or individual), type of sample, time and date of collection along with other pertinent information.
Shipping Requirements:	Transport or ship samples on ice in appropriate packagings.
Comments:	Additional tests recommended: <i>Staphylococcus aureus</i> Clinical Culture.

Test Name:	<u>Staphylococcus aureus, Streptococcus pyogenes Culture for Toxin Testing</u>
Lab and Phone #:	Bacteriology Reference Laboratory (617) 983-6607
Use of Test:	To determine if isolate is responsible for Toxic Shock Syndrome or a "Flesh Eating" Group A <i>Streptococcus</i> .
Special Instructions:	If <i>S. aureus</i> stool culture on food handlers is desired, prior consultation is required by calling (617) 983-6610.
Test Includes:	Confirmation of <i>S. aureus</i> and <i>S. pyogenes</i> and submitted to the CDC, Atlanta, GA for toxin testing on cultures that are confirmed with prior consultation.
Availability:	Monday through Friday.
Turnaround Time:	3 weeks to several months.
Sample:	Pure culture on an agar slant.
Forms Required:	Bacteriology Reference Laboratory Form or CDC Submission Form.

Shipping Requirements: Ship all submissions suspected to be positive as infectious substances. Ship at ambient temperatures using UN approved packagings. Mark and label the outer packaging as an infectious substance to conform with USPS and DOT regulations. See section on packaging and shipping specimens.

Test Name: **STEC (Shiga Toxin-Producing *E. coli*)**
See Shiga Toxin (Verotoxin) Assay.

Test Name: **Stool Culture**
See Enteric Pathogens, Routine Culture.

Test Name: **Streptococcus pneumoniae, Serotyping**
See Serotyping *Streptococcus pneumoniae*, *Streptococcus pyogenes* (M and T Typing).

Test Name: **Streptococcus pyogenes (Streptococcus sp. Serogroup A), M and T typing**
See Serotyping *Streptococcus pneumoniae*, *Streptococcus pyogenes* (M and T Typing).

Test Name: **Strongyloides Serology**
See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name: **Syphilis Serology**
See RPR (Rapid Plasma Reagin Card Test), Syphilis-VDRL-Cerebrospinal Fluid, (CSF), and TP-PA Antibody, (Treponema pallidum Particle Agglutination).

Test Name: **Syphilis VDRL-Cerebrospinal Fluid (CSF)**
Lab and Phone # Bacteriology Laboratory (617) 983-6600
Use of Test: To provide serologic evidence of neurologic exposure to syphilis. VDRL-CSF is the only standardized test for neurosyphilis. The VDRL test measures IgM and IgG antibodies to lipoidal material released from damaged host cells as well as to lipoproteinlike material, and possibly cardiolipin released from the treponemes. These antibodies are produced not only as a consequence to treponemal disease, but also in response to non-treponemal diseases in which tissue damage occurs.

Test Includes: Qualitative screening of non-treponemal (reagin) antibodies in spinal fluid. Quantitative titers are performed on positive screening samples.

Normal Range: Non-reactive.

Limitations: A negative result can occur in some neurosyphilis patients. Small amounts of blood or serum may cause a false positive result.

Availability: Usually run once per week.

Turnaround Time: 1 to 10 days

Sample and Volume: 1 to 3 mL of cerebrospinal fluid from a lumbar puncture into leakproof tubes.
Forms Required: Syphilis Serology Test Request Form SS-1 (09/00).
Sample Test Kit: Syphilis Serology Single Kit (holds one tube) or Syphilis Serology Multiple Kit (holds up to 9 tubes). These kits may be ordered by calling (617) 983-6640.
Sample Collection: Spinal tap, 1 to 3 mL, submitted in leak proof vials or tubes.
Shipping Requirements: Use double packaging system if transporting by couriers. Use triple packaging system if shipping using USPS and DOT regulations.

Test Name: *Taenia solium* Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **TB**
See Mycobacteriology (TB) listings.

Test Name: **Thermophilic Actinomycetes (Farmer's Lung)**
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **Toxic Shock, Toxin Testing for *Staphylococcus aureus*, *Streptococcus pyogenes***
See *Staphylococcus aureus*, *Streptococcus pyogenes* Culture for Toxin Testing.

Test Name: *Toxocara canis* Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: **TP-PA Antibody (*Treponema pallidum* Particle Agglutination)**
Lab and Phone #: Bacteriology Laboratory (617) 983-6600
Use of Test: Test is most commonly used for the detection of antibodies to *Treponema pallidum*. Testing is performed on specimens that are reactive with non-treponemal tests (e.g., RPR) and on specimens that are reactive by less commonly used antibody screening tests (e.g., Olympus PK).
Method of Test: TP-PA testing of specimens that are non-reactive with non-treponemal tests is limited and must be approved in advance by STD Laboratory staff.
Normal Range: More information may be obtained by calling (617) 983-6614.
Limitations: The TP-PA is a treponemal test for the serologic detection of antibodies to various species and subspecies of pathogenic *Treponema*, the causative agents of syphilis, yaws, pinta, bejel and endemic syphilis.

Non- Reactive.
In a small percentage of healthy individuals false positives may also appear. These are often transient and the cause is unknown. They may occur in association with other underlying illnesses. Positives may occur in individuals from areas where yaws or pinta was or is endemic. Treponemal

test results may remain positive for life and cannot be used to evaluate response to treatment or confirm reinfection.

Availability: Monday through Friday.

Turnaround Time: 1 to 5 Days.

Sample and Volume: Serum (\geq 3 mL) or whole blood (5 to 10 mL) collected in a red top or Serum Separator Tube (SST). Serum is preferable to whole blood. Use 13mm x 100mm or 16mm x 100mm tubes for collection. Allow blood to clot at least 30 minutes. Separate serum if centrifuge is available.

Forms Required: Syphilis Serology Test Request Form SS-1 (09/00).

Sample Test Kit: Syphilis Serology Single Kit (holds one tube) or Syphilis Serology Multiple Kit (holds up to 9 tubes). These kits may be ordered by calling (617) 983-6640.

Sample Collection: Venipuncture, collect 5 to 10 mL in a red top tube or SST. Use 13 mm x 100mm or 16mm x 100mm tubes for collection. Allow blood to clot at least 30 minutes. Separate serum if centrifuge is available.

Shipping Requirements: Serum may be shipped at room temperature, cold or frozen. Whole blood must be maintained at a temperature between 2°C and 27°C. Use triple packaging system if shipping by USPS. Use double packaging system if transporting by couriers.

Test Name: Trichinosis Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: Trypanosomiasis (South American) Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

Test Name: Tuberculosis
See Mycobacteriology (TB) listings.

Test Name: Tularemia
See *Francisella tularensis*, Culture and/or *Francisella tularensis*, Serology.

Test Name: Typhoid Fever (*Salmonella typhi*)
See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: Typhus Antibody
See Rickettsia Antibody Panel.

Test Name: Urine Culture, Mycobacteria
See Mycobacteria (TB) Smear and Culture (AFB).

Test Name:	<u>Varicella Zoster Antibody</u>
Lab and Phone #:	Virus Serology Laboratory (617) 983-6396
Use of Test:	Serodiagnosis of recent or current infection with this agent.
Test Includes:	Quantitative complement fixation IgG antibody testing for Varicella zoster virus.
Significant Result:	Seroconversion or four-fold increase in titer.
Limitations:	Anticomplementary activity may interfere.
Availability:	As required.
Turnaround Time:	2 to 7 days upon receipt of convalescent serum.
Sample and Volume:	3 mL of serum.
Forms Required:	Virus Serology Requisition Form.
Sample Test Kit:	Virus Serology Kit.
Sample Collection:	Acute and convalescent serum. See instructions in test kit.
Shipping Requirements:	Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **VDRL-CSF**
See Syphilis-VDRL-Cerebrospinal Fluid (CSF).

Test Name: **Verotoxin Assay**
See Shiga-toxin (Verotoxin) Assay.

Test Name: **Vibriosis**
See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: **Visceral Larva Migrans (Toxocariasis)**
See CDC Serology-Bacterial/Fungal/Protozoal.

Test Name: **West Nile Virus, Avian**
See Arbovirus PCR (Non-Human).

Test Name: **West Nile Virus Culture**
See Arbovirus Listings.

Test Name: **West Nile Virus EIA**
Lab and Phone #: **Virus Serology Laboratory** (617) 983-6396
Use of Test: Diagnosis of current infection with West Nile Virus.
Test Includes: Qualitative IgM capture EIA and IgG indirect EIA testing.
Significant Result: Positive IgM or seroconversion in IgG EIA. Confirmation by plaque reduction

Limitations: neutralization necessary.
Availability: May cross-react with other arboviruses.
Turnaround Time: As requested and routinely from May to October.
Sample and Volume: 2 to 5 days.
3 mL of serum, no additives. At least 1 mL of cerebrospinal fluid collected aseptically.
Forms Required: Virus Serology /Arbovirus Requisition Form.
Sample Test Kit: Virus Serology.
Sample Collection: **IgM:** Acute serum collected 1-3 days after onset; convalescent collected 8 or more days after onset may be necessary.
IgG: Acute serum may be used for testing but convalescent collected 8 or more days after onset may be necessary.
Shipping Requirements: Ship sample at refrigerated temperatures. Use double packaging system for transporting by Courier Service. Use triple packaging system for USPS. Apply a biohazard label and mark the outer container "Clinical Specimen" as appropriate. If the sample contains a known pathogen, use a triple packaging system and label and mark the outside of the container according to DOT and/or USPS regulations for infectious substances.

Test Name: **Whooping Cough**
See *Bordetella pertussis* and other *Bordetella* spp. Culture and/or *Bordetella pertussis* Serology.

Test Name: **Yersiniosis**
See Enteric Pathogens, Referred Culture and/or Enteric Pathogens, Routine Culture.

Test Name: **Zinc Protoporphyrin, (ZnPP) Whole Blood**
Lab and Phone #: **Environmental Chemistry/Childhood Lead Screening (617) 983-6665**
Use of Test: Indirect measure of lead poisoning and iron deficiency.
Method of Analysis: Hematofluorometry
Acceptable Range: Children 0 to 35 μ g/dL
Turnaround Time: 2 working days
Sample and Volume: 100 μ L whole blood; collect with EDTA; heparin is also acceptable.
Sampling Instructions: Call laboratory for sampling instructions.
Forms Required: Childhood Lead Screening Sample Submission Form.
Sample Container: Microcuvette capillary collection system, amber colored, coated with EDTA.
Call laboratory for supplies.
Sample Collection: Fingerstick or venipuncture. **EDTA** is the preferred anticoagulant.
Shipping Requirements: Keep samples refrigerated before mailing. Avoid exposing samples to extreme temperatures during shipping. Use double packaging system for transporting clinical diagnostic specimens by courier. Use triple packaging system when sending clinical blood samples by USPS. Use biohazard stickers on primary receptacles and outer packings. Label outer packings "Diagnostic Specimen Enclosed" as required by USPS and CDC.

Comments: Elevated in lead poisoning. See Centers for Disease Control guidelines for interpretation of Lead and Zinc Protoporphyrin blood levels at (<http://cdc.gov/nceh/lead/Publications>)

Test Name: Zygomycosis Serology
See CDC Serology–Bacterial/Fungal/Protozoal.

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Gonorrhea	37	Gonorrhea Culture	37
Gram Negative Bacteria	38	Bacterial Culture Identification	14
		Gram Negative Diplococci	38
Gram Positive Bacteria		Bacterial Culture Identification	14
Haemophilus ducreyi	39 - 40	Haemophilus ducreyi Culture	39
		Haemophilus ducreyi Direct Smear	40
Haemophilus influenzae	41	Haemophilus influenzae Culture	41
Hantavirus	41	Hantavirus IgM and IgG	41
Hemorrhagic colitis		Enteric Culture Referred Culture	32
		Enteric Culture Routine Culture	32
Herpes Simplex	42	Herpes Simplex Culture	42
		Herpes Simplex Group Antibody	42

Test Category	Page	Test Name	Page
Histoplasmosis		CDC Serology-Bacterial/Fungal/Protozoal	25
HIV-1	43– 45	HIV-1 Antibody Confirmation, OMT/Oral Fluid	43
		HIV-1 Antibody Confirmation, Serum	43
		HIV-1 Antibody Screen, OMT/Oral Fluid	44
		HIV-1 Antibody Screen, Serum	45
HIV-2	45 – 46	HIV-2 Antibody Confirmation, Serum Only	45
		HIV-2 Antibody Screen, Serum Only	46
Influenza	47 - 49	Influenza A Rapid Test	47
		Influenza Inhibition of Hemagglutination	47
		Influenza Rapid Culture	48
		Influenza Type A Antibody	48
		Influenza Type B Antibody	49
		Influenza/Parainfluenza Conventional Culture	49
Lead	50 - 52	Lead, Dust Wipes	50
		Lead, Paint Chips	50
		Lead, Pottery	50
		Lead, Soil	51
		Lead, Urine	51
		Lead, Water	51
		Lead, Whole Blood, Capillary Fingerstick	52
		Lead, Whole Blood, Venous Blood	52
Legionella	53	Legionella Culture	53
		Legionella Serology	53
Leishmaniasis		CDC Serology-Bacterial/Fungal/Protozoal	25
Leptospirosis		CDC Serology-Bacterial/Fungal/Protozoal	25
Listeria	54 - 55	Listeria Isolation, Food	54
<i>monocytogenes</i>		Listeria monocytogenes Culture	55
Lyme Disease	55	Lyme Disease, Western Blot IgM and IgG	55
Lymphocytic	56	Lymphocytic Choriomeningitis (LCM) Virus	56
Choriomeningitis		Culture and Serology	
Malaria	56	CDC Serology-Bacterial/Fungal/Protozoal	25
		Malaria Direct Smear	56
Measles	57 - 58	Measles Antibody	57
		Measles IgM Antibody	57
		Measles Total Antibody (IgM and IgG)	58
		Measles Virus Culture	58
Mercury	59	Mercury, Urine	59
Mucormycosis		CDC Serology-Bacterial/Fungal/Protozoal	25
Mumps	59 - 61	Mumps Antibody	59
		Mumps Culture	60
		Mumps IgG IFA	60
		Mumps IgM and IgG EIA	61
Murine Typhus		Rickettsia Antibody Panel	73

Test Category	Page	Test Name	Page
<i>Mycobacteria</i> spp.	61 - 66	<i>CDC Culture Identification, Mycobacteriology</i>	25
		<i>Mycobacteria</i> spp., Stock Culture	61
		<i>Mycobacteriology, (MAC) Identification by Accuprobe</i>	62
		<i>Mycobacteriology, (MTD) Mycobacterium tuberculosis</i> Direct	62
		<i>Mycobacteriology, (TB) Identification (Referred Culture)</i>	63
		<i>Mycobacteriology, (TB) Smear</i>	63
		<i>Mycobacteriology, (TB) Smear and Culture (AFB)</i>	64
		<i>Mycobacteriology, (TB) Susceptibility</i>	65
		<i>Mycobacteriology, (TB) Susceptibility Rapid</i>	66
<i>Mycoplasma pneumoniae</i>	66	<i>Mycoplasma pneumoniae</i> Antibody	66
<i>Neisseria gonorrhoeae</i>		Gonorrhea Culture	37
<i>Neisseria Meningitidis</i>	66	<i>Neisseria meningitidis</i> Culture	67
<i>Nocardia</i>	67	<i>CDC Serology-Bacterial/Fungal/Protozoal Nocardia</i>	25 67
<i>Paracoccidioidomycosis</i>		CDC Serology-Bacterial/Fungal/Protozoal	25
<i>Paragonimiasis</i>		CDC Serology-Bacterial/Fungal/Protozoal	25
<i>Parainfluenza</i>	67	<i>Parainfluenza 1, 2, 3, Antibody</i>	68
<i>Parasitic Serology</i>		CDC Serology-Bacterial/Fungal/Protozoal	25
<i>Parvovirus</i>	68	<i>Parvovirus B19 IgM and IgG Antibody</i>	68
<i>Pertussis</i>		<i>Bordetella pertussis</i> and other <i>Bordetella</i> spp. Culture	17
		<i>Bordetella Pertussis Serology</i>	17
<i>Pesticides</i>	69	Pesticides and Industrial Chemicals in Food	69
<i>Plague</i>		CDC Serology-Bacterial/Fungal/Protozoal	25
<i>Plesiomonas shigelloides</i>		<i>Enteric Pathogens, Referred Culture</i>	32
<i>Poliovirus</i>		Enterovirus Culture	34
<i>Polychlorinated biphenyls</i>	69	<i>Polychlorinated biphenyls (PCB), Serum</i>	69
<i>Psittacosis</i>		<i>Chlamydia psittaci</i> Antibody	27
<i>Pulsed Field Gel Electrophoresis</i>		Bacterial Typing, Pulsed Field Gel Electrophoresis (PFGE)	15
<i>Q Fever</i>	70	Q Fever Antibody	70
<i>Rabies</i>	70	Rabies Test, Antigen Detection, Human	70
		Rabies Test, Antigen Detection, Non-Human	71
<i>Respiratory Syncytial Virus</i>	72	Respiratory Viruses Antibody Panel	72
		RSV Antibody	74
<i>Rickettsia</i>	73	Rickettsia Antibody Panel	73

Test Category	Page	Test Name	Page
RPR	73	RPR, (Rapid Plasma Reagin Card Test), Non-treponemal Syphilis Serology Test	73
RSV	74	Respiratory Viruses Antibody Panel	72
		RSV Antibody	74
Rubella	75 - 76	Rubella Antibody	75
		Rubella IgM Antibody	75
		Rubella Virus Isolation	76
Rubeola		Measles Antibody	57
		Measles IgM Antibody	57
		Measles Total Antibody (IgM and IgG)	58
		Measles Virus Culture	58
Salmonella	76	Salmonella Isolation, Food	76
Salmonellosis		Enteric Pathogens, Routine Culture	32
		Enteric Pathogens, Referred Culture	32
Schistosomiasis		CDC Serology-Bacterial/Fungal/Protozoal	25
Serotyping	77	Enteric Pathogens, Referred Culture	32
		Serotyping <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i> (M and T Typing)	77
Shiga Toxin	78	Shiga Toxin (Verotoxin) assay	78
Shigella	79	Shigella Isolation, Food	79
Shigellosis		Enteric Pathogens, Routine Culture	32
		Enteric Pathogens, Referred Culture	32
Sporotrichosis		CDC Serology-Bacterial/Fungal/Protozoal	25
Staphylococcus aureus	79 - 80	Enteric Pathogens, Routine Culture	32
		<i>Staphylococcus aureus</i> Plate Count, Food	80
		<i>Staphylococcus aureus</i>, <i>Streptococcus pyogenes</i> Culture for Toxin Testing	80
STEC		Shiga Toxin (Verotoxin) assay	78
Stool Culture		Enteric Pathogens, Routine Culture	32
Streptococcus pneumoniae		Serotyping <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i> (M and T Typing)	77
Streptococcus pyogenes		Serotyping <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i> (M and T Typing)	77
Strongyloides		CDC Serology-Bacterial/Fungal/Protozoal	25
Syphilis		RPR, (Rapid Plasma Reagin Card Test), Non-treponemal Syphilis Serology Test	73
		Syphilis VDRL – Cerebrospinal Fluid (CFS)	81
		TP - PA Antibody (<i>Treponema pallidum</i> Particle Agglutination)	82
Taenia solium		CDC Serology-Bacterial/Fungal/Protozoal	25
Thermophilic Actinomycetes		CDC Serology-Bacterial/Fungal/Protozoal	25
Toxocara canis		CDC Serology-Bacterial/Fungal/Protozoal	25
Treponema pallidum	82	TP - PA Antibody (<i>Treponema pallidum</i> Particle Agglutination)	82

Test Category	Page	Test Name	Page
Trichinosis		CDC Serology-Bacterial/Fungal/Protozoal	25
Trypanosomiasis		CDC Serology-Bacterial/Fungal/Protozoal	25
Tuberculosis		CDC Culture Identification, Mycobacteriology	25
		Mycobacteria spp., Stock Culture	61
		Mycobacteriology, (MAC) Identification by Accuprobe	62
		Mycobacteriology, (MTD) <i>Mycobacterium tuberculosis</i> Direct	62
		Mycobacteriology, (TB) Identification (Referred Culture)	63
		Mycobacteriology, (TB) Smear	63
		Mycobacteriology, (TB) Smear and Culture (AFB)	64
		Mycobacteriology, (TB) Susceptibility	65
		Mycobacteriology, (TB) Susceptibility Rapid	66
Tularemia		<i>Francisella tularensis</i> Culture	35
		<i>Francisella tularensis</i> Serology	36
Typhoid Fever		Enteric Pathogens, Referred Culture	32
		Enteric Pathogens, Routine Culture	32
Typhus		Rickettsia Antibody Panel	73
Urine, Culture		Mycobacteriology, (TB) Smear and Culture (AFB)	63
Varicella Zoster	84	Varicella Zoster Antibody	84
VDRL		Syphilis VDRL-Cerebrospinal Fluid (CFS)	81
Verotoxin Assay		Shiga-toxin (Verotoxin) Assay	78
Vibriosis		Enteric Pathogens, Referred Culture	32
		Enteric Pathogens, Routine Culture	32
Visceral Larva Migrans		CDC Serology-Bacterial/Fungal/Protozoal	25
West Nile Virus		Arbovirus Culture, Avian	9
		Arbovirus Culture, Human	9
		Arbovirus Culture, Other	10
		Arbovirus PCR, Avian	10
		Arbovirus PCR, Other	11
		Arbovirus Plaque Reduction Neutralization Test-Antibody (PRNT)	11
		Arbovirus Plaque Reduction Neutralization Test-Virus (PRNT)	11
		West Nile Virus EIA	85
Whooping Cough		<i>Bordetella pertussis</i> and other <i>Bordetella</i> spp., Culture	17
		<i>Bordetella pertussis</i> Serology	17
Yerseniosis		Enteric Pathogens, Referred Culture	32
		Enteric Pathogens, Routine Culture	32
Zinc Protoporphyrin	86	Zinc Protoporphyrin, (ZnPP)	85
Zygomycosis		CDC Serology-Bacterial/Fungal/Protozoal	25

TEST KITS - GENERAL INFORMATION:

The State Laboratory Institute supplies mailing containers to physicians, hospital laboratories, clinics and boards of health throughout the Commonwealth **for the purpose of submitting samples to the SLI**. These containers are the property of the MDPH/SLI and should not be used for purposes other than shipping specimens to the SLI. The SLI does not supply blood collection tubes for use in the collection of blood samples for serological testing. All mailing containers supplied by the SLI meet U.S. Postal Service (USPS) and Department of Transportation (DOT) regulations. The SLI supplies only triple container kits because specimens usually must be packed in this manner with sufficient absorbent material enclosed to absorb the entire volume of liquids. Page 98 of this manual contains packing instructions for local surface transport of clinical diagnostic specimens and page 99 contains instructions for local surface transport of infectious substances. Each procedure contains specific directions on correct packaging, marking, labeling and shipping of specimens for transport by courier service (DOT) or the United States Postal Service (USPS). If the sample you are sending to the SLI is for the purpose of confirming an already identified pathogen, ship the specimen as an infectious substance. If your package contains an infectious substance and is going to be transported on an airplane, you must follow International Air Transport Association Regulations (IATA). See the next section for specific carrier instructions.

The following guidelines may help to avoid problems associated with sample collection and submission:

- Please note the sample and volume, the correct requisition form required, the sample container, the sample test kit and the shipping requirements suggested in each test profile for the safe and expeditious transport of your samples to the SLI.
- It is the responsibility of the provider to submit good quality samples for analysis.
- All samples submitted for analysis should be properly labeled for identification. The name on the primary, leakproof, sterile container (the sample collection tube or vial) and the name on the laboratory requisition form must be the same.
- A completed requisition form containing necessary and pertinent information must accompany each specimen submitted.
- Place the requisition form between the secondary and outer container. Do not attach the sample to the requisition or wrap the requisition form around the sample.
- Specimens should be collected at the appropriate times noted in the test profile. This is important for serological testing.
- Follow instructions for temperature control. Maintain cool temperatures where noted by using cold packs. Do not expose samples to extreme temperatures.
- Do not hold onto specimens for long periods. Transport or ship the samples to the laboratory as early as possible. Avoid mailing specimens on weekends or holidays.
- Make sure the correct laboratory name is printed on the return address label. Please cross out any laboratory name that does not apply.

The following is a list of sample test kits, as noted in the test profiles, available from the SLI. The test kit along with the amount of kits per case is noted. Please call or fax an order using the appropriate number. To obtain environmental test kits, available for a fee, please call the laboratory listed for instruction.

TEST KITS:

Below is a listing of sample test kits and materials available for the purpose of mailing samples to the State Laboratory Institute:

Sample Test Kit:	Per Case	Laboratory	Phone # 617	Fax # 617	Fee
Chlamydia LCX	12 kits	Bacteriology Laboratory	983-6600	983-6618	None
Enteric	6 kits	Bacteriology Laboratory	983-6640	983-6618	None
HCV Multiple Courier	12 kits	HIV Laboratory	983-6390	983-6363	None
HCV Multiple Mailing	9 kits	HIV Laboratory	983-6390	983-6363	None
HCV Single Mailing	24 kits	HIV Laboratory	983-6390	983-6363	None
HIV Multiple Courier	12 kits	HIV Laboratory	983-6390	983-6908	None
HIV Multiple Mailing	9 kits	HIV Laboratory	983-6390	983-6908	None
HIV Single Courier	24 kits	HIV Laboratory	983-6390	983-6908	None
HIV Single Mailing	24 kits	HIV Laboratory	983-6390	983-6908	None
Legionella Transport	4 kits	Bacteriology Reference Lab	983-6640	983-6618	None
Pertussis Culture	Each	Bacteriology Reference Lab	983-6640	983-6618	None
Pertussis Serology	6 kits	Bacteriology Laboratory	983-6640	983-6618	None
Subculture / Infectious Substance	6 kits	Bacteriology Laboratory	983-6640	983-6618	None
Syphilis Serology Multiple Courier	12 kits	Bacteriology Laboratory	983-6640	983-6618	None
Syphilis Serology Multiple Mailing	9 kits	Bacteriology Laboratory	983-6640	983-6618	None
Syphilis Serology Single Courier	24 kits	Bacteriology Laboratory	983-6640	983-6618	None
Syphilis Serology Single Mailing	24 kits	Bacteriology Laboratory	983-6640	983-6618	None
TB Culture Courier	25 kits	Mycobacteriology Lab	983-6358	983-6399	None
TB Culture Mailing	16 kits	Mycobacteriology Lab	983-6358	983-6399	None
Throat Culture	Each	Bacteriology Laboratory	983-6600	983-6618	None
Virus Transport Medium - Influenza	Each	Epidemiology & Immunization Division	983-6848	983-6840	None
Virus Transport Medium	Each	Virus Isolation Laboratory	983-6382	983-6363	None
Virus Serology	9 kits	Virus Serology Laboratory	983-6396	983-6363	None
West Nile Virus, Avian Supplied to BOH Agents	5 kits	Vector-Borne Disease Lab	983-6391	983-6363	None
Forms Available:					
HIV Barcodes		HIV Laboratory	983-6390	983-6363	None
Premarital Forms		STD Control	983-6940	983-6962	None
Syphilis Serology Forms Provided to Select Clinics Only		STD Laboratory	983-6614	983-6618	None
Lead, Order Form for Environmental Kits		Analytical Chemistry	983-6654	983-6662	None
Lead, Paint Worksheet		Analytical Chemistry	983-6654	983-6662	None
Lead, Soil Worksheet		Analytical Chemistry	983-6654	983-6662	None
Blood Lead Screening Supplies:					
Lead, Microcuvette Capillary Collection Tubes		Childhood Lead Screening	983-6665	983-6677	None
Lead, Blood Requisition Form		Childhood Lead Screening	983-6665	983-6677	None
Mailers: Boxes		Childhood Lead Screening	983-6665	983-6677	None
Mailers: Padded Envelopes		Childhood Lead Screening	983-6665	983-6677	None
Environmental Test Kits:					
Lead, Dust Wipes	5/kit	Analytical Chemistry	983-6654	983-6662	\$60.00 / Kit
Lead, Water	3/kit	Analytical Chemistry	983-6654	983-6662	\$42.50 / Kit
Lead, Sodium Sulfide (Provided to State Licensed Lead Inspectors and Code Enforcement Agents Only).	Each	Analytical Chemistry	983-6654	983-6662	\$12.50 / Kit

PACKAGING AND SHIPPING SPECIMENS:

INTRODUCTION: Employees responsible for shipping laboratory specimens must maintain diagnostic specimens and infectious substances in suitable condition from shipper to consignee. In order to accomplish this, the employee must properly identify, classify, pack, mark, label and document each shipment in accordance with multiple federal and international regulations so as to ensure expeditious transport and timely, accurate test results.

Because diagnostic specimens and infectious substances are considered dangerous goods when transported by air the International Air Transport Association, (IATA) Dangerous Goods Regulations apply. The IATA regulations require that persons responsible for shipping diagnostic specimens and infectious substances by air be trained and certified.

DEFINITIONS:

Diagnostic Specimen: Any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, excluding live infective animals. A diagnostic sample is a routine, clinical, non-pathogenic specimen, with no or low risk to both the individual and the community. Specimens of diagnostic nature would include samples being submitted for routine blood lead analysis, genetic screening, blood glucose determinations and the like.

Infectious Substance: A substance, clinical specimen or culture, isolate, or other derivative of a clinical specimen that contains or is suspected of containing a viable infectious virus, prion, or a viable microorganism, such as a bacterium, rickettsia, parasite or fungus, that is known or reasonably believed to cause disease in humans. This includes:

- All cultures containing or suspected of containing a microorganism that causes or may cause disease in humans.
- All human or animal clinical specimens that are known or suspected of containing an infectious microorganism or toxin.
- All samples from a patient with serious disease of unknown cause.
- Environmental samples to the extent that they are suspected of containing human pathogens at a level that presents a risk of infection.
- Other specimens designated as infectious by a qualified person such as a physician, scientist or nurse.

Toxins known to be pathogenic are to be packaged and shipped either as infectious substances or as special infectious substances as applicable.

Risk Groups:

- Risk Group 1: Diagnostic specimen. A micro-organism that is unlikely to cause human or animal disease and is considered **no or low individual or community risk**.
- Risk Group 2: A pathogen that can cause human or animal disease unlikely to be a serious hazard but capable of causing serious infection on exposure. Effective treatment and preventative measures are available; the risk of spread of infection is limited; and there is **moderate individual risk and low community risk**.
- Risk Group 3: A pathogen that causes serious human or animal disease. The disease does not ordinarily spread from one infected individual to another; effective treatment and preventative measures are available; and there is **high individual and low community risk**.
- Risk Group 4: A pathogen that causes serious human or animal disease. The pathogen is readily transmitted from one individual to another directly or indirectly; effective treatment and preventable measures are not usually available; and there is **high individual and community risk**.

Special Infectious Substance: Any of the microbiological agents or toxins listed in Section 72.5 (Additional Requirements For Facilities Transferring Or Receiving Select Agents) or Appendix A to 42 CFR, Part 72. These special infectious substances include those agents listed in the CDC/NIH publication "Biosafety in Biomedical Laboratories", as biosafety level (BSL) 4 and most of the BSL 3 agents. Special infectious substances present a high risk of infection and/or death to persons exposed to them either through direct contact, aerosol or ingestion. Shipments of special infectious substances must be tracked to assure their safe arrival.

Select Agents: Some organisms listed as special infectious substances are also considered "select agents" and are regulated in USPHS 42 CFR Part 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents). The shipper and receiver of select agents must be registered with the Centers for Disease Control (CDC) and advance arrangements must be made between the shipper and consignee and the shipper and the operator.

These substances must be tracked to ensure safe delivery. A listing of select agents is included as an attachment to this document.

Hazardous Material: A substance or material in a quantity and form that may pose an unreasonable risk to health and safety or property when transported in commerce. This term is more commonly used for domestic shipments in the United States (DOT) and is synonymous with the international use of dangerous goods in terms of classification of materials/goods. See definition of dangerous goods.

Dangerous Goods: Articles or substances capable of posing a significant risk to health, safety or property when transported by air and which meet the criteria of one or more of nine UN hazard classes and one of three UN packaging groups according to IATA Dangerous Goods Regulations, Section 3.0. The nine classes relate to the type of hazard whereas the packing group relates to the degree of danger within the class, with packing group 1 presenting the greatest danger. Substances in Class 6, Division 6.2 are not assigned packing groups but are categorized by risk group.

- Class 1** - Explosives
- Class 2** - Gases
- Class 3** - Flammable Liquids
- Class 4** - Flammable Solids
- Class 5** - Oxidizing Substances
- Class 6** - **Toxic and Infectious Substances**
 - Division 6.1 - Toxic Substances
 - Division 6.2 - Infectious Substances**
- Class 7** - Radioactive Material
- Class 8** - Corrosives
- Class 9** - Miscellaneous Goods

Ex: **Carbon dioxide, solid (dry ice)**

Labeling: Information concerning the contents of the package and associated hazards; usually printed on paper and affixed to the exterior surface of the package.

Marking: Information about the contents and shipment of a package that is printed on or affixed to the exterior surface of a package.

Overpack: An enclosure used by a single shipper to contain one or more packages and to form one handling unit for convenience. Dangerous goods packages contained in the overpack must be properly packed, marked, labeled and in proper condition. For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of IATA Packing Instruction 904.

Package: The complete product of the packing operation consisting of the packaging and contents prepared for transport.

Packaging: Receptacles and any other components or materials necessary for the receptacle to perform its containment function and to ensure compliance with the minimum packing requirements of the applicable regulations.

- All packagings (new and reused) must be constructed of good quality. The exterior of the outer packaging, where applicable for infectious substances, must clearly state that the packagings meet UN Specifications for Division 6.2 Infectious Substances. All packagings must withstand leakage of contents, punctures, shocks, sudden pressure changes and must resist the effects of temperature, humidity, pressure and vibrations found in normal conditions of transport. Any contaminated packagings must not be reused. Any reusable packagings found to be defective must be discarded.
- Supplies needed. (See individual packaging instructions).

LOCAL SURFACE TRANSPORT OF A CLINICAL DIAGNOSTIC SPECIMEN

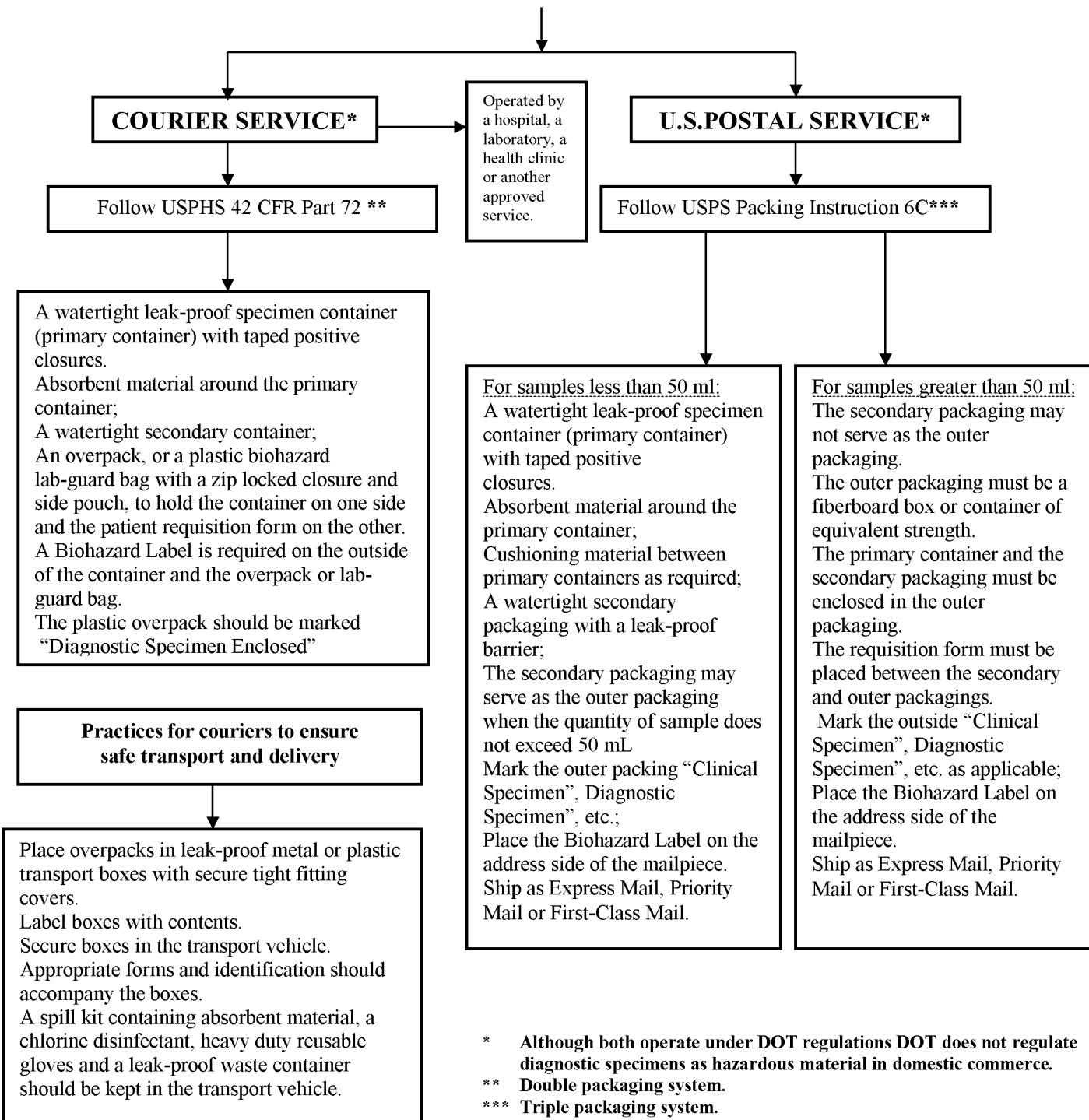
Transport of samples from:

A physician's office to a laboratory;

A hospital to a diagnostic laboratory;

A clinic to a public health laboratory;

A private laboratory or hospital laboratory to a public health laboratory



* Although both operate under DOT regulations DOT does not regulate diagnostic specimens as hazardous material in domestic commerce.

** Double packaging system.

*** Triple packaging system.

LOCAL SURFACE TRANSPORT OF AN INFECTIOUS SUBSTANCE

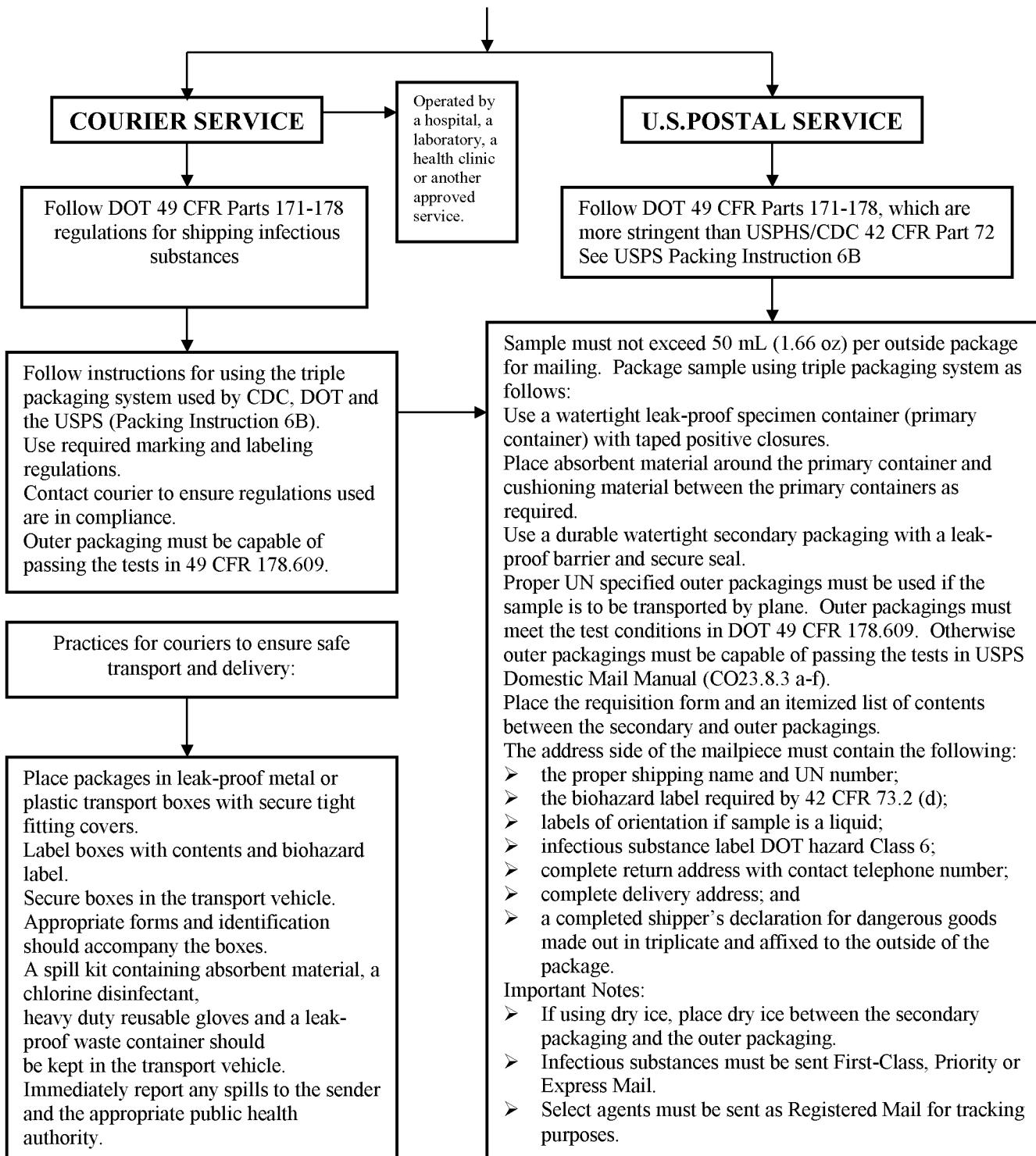
Transport of samples from:

A physician's office to a laboratory;

A hospital to a diagnostic laboratory;

A clinic to a public health laboratory;

A private laboratory or hospital laboratory to a public health laboratory



**SPECIFIC CARRIER INSTRUCTIONS FOR PACKAGING AND SHIPPING DIAGNOSTIC
SPECIMENS AND INFECTIOUS SUBSTANCES:**

I. UNITED PARCEL SERVICE-UPS

a) DIAGNOSTIC SPECIMEN:

NOTE: UPS will accept Diagnostic Samples for delivery if they are packaged according to DOT Division 6.2 Hazardous Materials Regulations for Infectious Substances.

MANDATORY PACKAGING REQUIREMENTS:

- A watertight primary container.
- A watertight secondary container.
- An absorbent material to absorb any liquid being shipped.
- A sturdy third package or outer container.
- An overwrap:

The package must be placed into a **UPS, Next Day Air, Laboratory Pak** marked "**Diagnostic Specimen Enclosed**" on the front of the overwrap.

SPECIAL MARKING REQUIREMENTS:

- The words, "Diagnostic Specimen Enclosed" must be marked on the outside of the overwrap.
- The outside of the outer package must bear the markings that clearly identify the package as one that meets **UN Specifications for Division 6.2 Infectious Substances**.
- An example of markings which clearly identify the package as meeting UN specifications for shipment of Infectious Substances:



Similar markings must be on the outer packagings used to ship Diagnostic Specimens by UPS.

SPECIAL LABELING REQUIREMENTS:

- The outside of the third container must contain the **International Biohazard Symbol Label** with either a fluorescent orange or fluorescent red background.
- **Labels of orientation** must be used for **liquid** samples.

SPECIAL SHIPPING REQUIREMENTS:

- Enclose a completed **UPS Airway Bill**.
- Indicate that **Diagnostic Specimens are enclosed** on the airway bill.
- No other shipping papers are required.

NOTE (1): UPS does not ship diagnostic specimens internationally. The UPS Laboratory Pak is to be used only for domestic and Puerto Rico UPS Next Day Air Shipments.

NOTE (2): Anything labeled 6.2, Infectious Substance and/or containing dry ice, cannot be shipped inside the UPS Diagnostic Specimen Laboratory Pak.

NOTE (3): When using dry ice, use sturdy packaging meeting UN Specifications for the outer packaging. When shipping samples in dry ice for medical or diagnostic purposes, mark the outside of the package and the airway bill, "**Material being refrigerated for medical or diagnostic purposes**". You do not need to use the Class 9 Miscellaneous Label.

UNITED PARCEL SERVICE - UPS INFECTIOUS SUBSTANCES:

**NOTE: UPS WILL NOT DELIVER OR ACCEPT FOR DELIVERY ANY INFECTIOUS SUBSTANCES.
YOU MUST USE ANOTHER CARRIER FOR TRANSPORT.**

UPS does not accept nor pick up any packaging which includes the diamond label bearing the words "Infectious Substance"

I. UNITED PARCEL SERVICE – UPS b) DRIED BLOOD SPECIMENS:

Clinical specimens collected by carefully applying a few drops of blood, freshly drawn by finger stick or heel prick with a lancet, onto absorbent specimen collection (filter) paper.

Diagnostic Specimen:

- Dried blood spot specimens can be shipped or transported with no reasonable expectations of occupational exposure to blood or other potentially infectious material. See **CDC Guidelines for the Shipment of Dried Blood Spot Specimens**, page 3, Risk Evaluation.
- After drying, enclose standard filter paper collection kits (each kit contains a sturdy paper overlay that covers the absorbent filter paper containing the dried specimen), in a high quality paper mailer provided by UPS and seal.
- Fill out UPS Airway Bill and attach to paper mailer, (letter).
- Paper mailers should be extra-strong, tear-proof, air-permeable, and water-resistant envelopes.
- Do not use leak-proof plastic bags because heat buildup and accumulation of moisture within the bag may adversely affect the dried specimen.

Infectious Substance:

- Do not ship by UPS.
- See packaging requirements of the United States Postal Service.

For more information please see the following references:

US Postal Service Domestic Mail Manual, Issue 52, dated 07/01/97, Regulation CO23.10.7 Hazardous Matter.

Guidelines for the Shipment of Dried Blood Spot Specimens, Safety & Health Monograph, Office of Health and Safety, Centers for Disease Control and Prevention (CDC), May 1993.

Procedure for the handling and transport of diagnostic specimens and etiologic agents, Third edition, Approved standard. NCCLS document H5-A3. NCCLS, Wayne, PA, May 1994.

For additional information, call the UPS Hazardous Materials Support Center at 1-800-554-9964. To order Laboratory Paks, call 1-800-PICK-UPS. Visit the UPS Website at: (www.ups.com)

II. FEDERAL EXPRESS – FedEx

a) DIAGNOSTIC SPECIMEN:

NOTE: FedEx will accept diagnostic samples for delivery if they are packaged according IATA regulations. See IATA packing instruction number 650, packaging diagnostic samples.

MANDATORY PACKAGING REQUIREMENTS:

- A watertight primary receptacle(s). All primary receptacles must have positive closures (such as screw-on, snap-on, or push-on caps) that must be taped.
- A watertight secondary container or packaging.
- An absorbent material placed between the primary receptacle(s) and the secondary container to absorb any liquid being shipped.
- If multiple primary receptacles are placed in the same secondary receptacle, they must be individually wrapped to prevent contact between them.
- Use enough absorbent material must be used to absorb the entire contents of all of the primary receptacles.
- A sturdy third, outer container or package.
- The package size must accommodate all labels, markings and documentation.
- An overwrap - the package must be placed into a **FedEx, Diagnostic Specimen Envelope** marked **"Diagnostic Specimen"** on the front.

SPECIAL MARKING REQUIREMENTS:

- Diagnostic Specimen Enclosed, must be clearly marked on the outside.

SPECIAL LABELING REQUIREMENTS:

- The outside of the third container must contain the International Biohazard Symbol **Label** with either a fluorescent orange or fluorescent red background. This label must be on containers used for shipping human blood, human blood products, unfixed human tissues, semen, fluids from body cavities and joints, as well as any human body fluids containing visible blood.
- **Labels of orientation** must be used for **liquid** samples.

SPECIAL SHIPPING REQUIREMENTS:

- Enclose a completed Federal Express Air Bill.
- Note on the Airway Bill **"Diagnostic Specimens Enclosed."**

NOTE: Anything labelled 6.2, Infectious Substance and/or containing Dry Ice, cannot be shipped inside the Diagnostic Specimen Envelope.

II. FEDERAL EXPRESS – FedEx**b) INFECTIOUS SUBSTANCE:**

- **Risk Group 2**
- **Risk Group 3**

NOTE: FedEx will accept Infectious Substances in Risk Group 2 and in Risk Group 3 for delivery, if they are packaged according to IATA regulations. See IATA packing instruction number 602, packaging infectious substances. FedEx will not accept any Risk Group 4 infectious substances, as these must follow stricter notification policies. You will have to find another carrier to transport infectious substances in Risk Group 4. **IMPORTANT:** FedEx requires all Shipper's Declarations to be typed.

MANDATORY PACKAGING REQUIREMENTS (Risk Group 2 and 3):

- A watertight primary receptacle(s). All primary receptacles must have positive closures (such as screw-on, snap-on or push-on caps) that must be taped.
- A watertight secondary container or packaging.
- An absorbent material placed between the primary receptacle(s) and the secondary container to absorb any liquid being shipped.
- If multiple primary receptacles are placed in the same secondary receptacle, they must be individually wrapped to prevent contact between them.
- Enough absorbent material must be used to absorb the entire contents of all of the primary receptacles.
- Absorbent material is not required for solid substances.
- A sturdy third, outer container or package consisting of corrugated fiberboard, wood, metal or rigid plastic.

- The package FedEx will accept must be large enough in size to accommodate all markings, labelling and the FedEx documentation. The shipper's declaration may be folded in half and placed into the air waybill pouch with the air waybill.
- All packing materials must meet **UN Specifications for Division 6.2 Infectious Substances**.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

SPECIAL MARKING REQUIREMENTS:

Note: IATA recommends markings be at least 12mm high, except packages of 30L or 30kg capacity or less must be 6 mm minimum height.

- The **Proper Shipping Name** (with the technical name). Example, **Infectious substance, affecting humans**, (Hepatitis B Virus).
- The UN Number, example **UN 2814**
- **Full name and address** of the shipper (**From**) and the Consignee (**To**) marked on the top or side of the package.
- The **name and telephone number** of a person **responsible** for the shipment.
- The package must be marked if using dry ice, (**Carbon Dioxide, solid**), **UN 1845**.
- The **net weight** of dry ice in the package must be recorded on the outside of the outer package.
- The outside of the outer package must bear the markings that clearly identify the package as one that meets **UN Specifications for Division 6.2 Infectious Substances**.
- Overpacks containing Dry Ice must state "**Inner Packages Comply with Prescribed Specifications**".

SPECIAL LABELING REQUIREMENTS:

- Arrows or **Package Orientation Labels** are required on combination packages containing liquid. (An exception is infectious substances in primary receptacles of 50 mL or less). When arrows are required, there must be two, one on opposite sides of the package.
- **Hazard label for Infectious Substances, Class 6**.
- **Hazard label for Dry Ice, Miscellaneous, Class 9**, if used.
- **Cargo Aircraft only label**, as it applies. If you are shipping more than 50 mL or 50 g of infectious substance, you need to use the Cargo Aircraft only label, as the shipment will be restricted to cargo. Cross off passenger and cargo on the shipper's declaration. When shipping less than 50 mL or 50 g, you do not need a cargo label and you need to cross off cargo only on the documentation.

SPECIAL SHIPPING REQUIREMENTS:

- **The shipper must make advance arrangements with the consignee and the operator** (carrier), to ensure that the shipment can be transported and delivered without delay.
- **Complete** and attach a **Federal Express Shippers Declaration**, place it to a pouch, and attach the pouch to the outside of the outer package.
- **Enclose a completed Federal Express Airway Bill**, place it into the pouch containing the shipper's declaration and attach the pouch to the package.

NOTE:

Federal Express is a Cargo Airline. Regardless where your package is being shipped, (even if it is only moving 30 miles down the road), it will be shipped under IATA Regulations for Dangerous Goods. Therefore you must package your shipment accordingly as if it were to be shipped by air.

For more information, call 1-800-GO-FedEx (Ext. 1666) or 800-463-3339 and ask for the Dangerous Goods Hotline or the FedEx Packaging Department at 1-800-633-7019. Website: (www.fedex.com)

III. UNITED STATES POSTAL SERVICE – USPS

a) DIAGNOSTIC SPECIMEN: 50 mL or less

NOTE: The USPS will accept Diagnostic Samples for delivery if when packaged according to Hazardous, Restricted, and Perishable Mail, Publication 52, Regulation 346.32, (see USPS Packaging Instruction 6C), and the Domestic Mail Manual Regulation CO23.8.0, for Infectious Substances.

MAILABILITY:

- **International Mail:** Only as permitted when written approval has been granted prior to mailing. Prepare for mailing using USPS packing instruction 6B for infectious substances.
- **Domestic Mail:** Permitted only via **Express Mail, Priority Mail, or First-Class Mail** service.

MANDATORY PACKAGING REQUIREMENTS (USPS Packing Instruction 6C For Diagnostic

Specimens Not Exceeding 50 mL Per Mailpiece):

- A watertight primary receptacle must be durable and securely sealed.
- An absorbent material capable of absorbing any leakage of liquid being shipped must surround the primary receptacle and be sufficient to withstand shock and pressure changes.
- Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.
- A watertight secondary packaging with a leakproof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- The secondary packaging may serve as the outer packaging when the quantity of specimen does not exceed 50 mL (1.66 ounces) per mailpiece.

SPECIAL MARKING REQUIREMENTS:

The **full name and address** of the shipper (**From**) and the Consignee (**To**) must be placed on the top or side of the package. The address side must be clearly marked **“Clinical Specimen, Blood Sample”**, **“Clinical Specimen, Urine Sample”**, **“Clinical Specimen, Saliva Sample”**, **“Biological Product”**, etc. where applicable.

SPECIAL LABELING REQUIREMENTS:

- The address side of the outer package must contain the **International Biohazard Symbol Label** with either a fluorescent orange or fluorescent red background.
- **Labels of orientation** must be used for liquid samples.

SPECIAL SHIPPING REQUIREMENTS:

- A Shipper's Declaration is not required for clinical specimens and biological products that do not contain infectious substances.

III. UNITED STATES POSTAL SERVICE – USPS

b) DIAGNOSTIC SPECIMEN:

USPS PACKING INSTRUCTION 6C, (CONTINUED)

MANDATORY PACKAGING REQUIREMENTS (USPS Packing Instruction 6C

For Diagnostic Specimens Exceeding 50 mL Per Mailpiece):

- A watertight primary receptacle must be durable and securely sealed.
- A single primary receptacle must not contain more than 1,000 mL of a specimen. Multiple primary receptacles are permitted provided a single mailpiece does not contain more than 4,000 mL.
- An absorbent material must surround the primary receptacle or be otherwise configured to absorb all of the liquid content in the primary receptacle in case of leakage.
- Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.
- A watertight secondary packaging with a leakproof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- The primary receptacle(s) and the absorbent cushioning must be enclosed in the secondary packaging.
- The secondary packaging can not serve as the outer packaging.

- The outer packaging must be a fiberboard box or a container of equivalent strength.
- The primary receptacle(s), the absorbent cushioning, and the secondary packaging must be enclosed in the outer packaging.
- A single outer packaging must not contain more than 4,000 mL of the specimen material.

SPECIAL MARKING REQUIREMENTS:

- The full name and address of the shipper (From) and the Consignee (To) on the top or side of the package.
- The address side must be clearly marked "Clinical Specimen, Blood Sample", "Clinical Specimen, Urine Sample", "Clinical Specimen, Saliva Sample", "Biological Product", etc. where applicable.

SPECIAL LABELING REQUIREMENTS:

- The address side of the outer package must contain the **International Biohazard Symbol Label** with either a fluorescent orange or fluorescent red background.
- **Labels of orientation** must be used for **liquid** samples.

SPECIAL SHIPPING REQUIREMENTS:

- A Shipper's Declaration for dangerous goods is not required for clinical specimens and biological products that do not contain infectious substances.

III. UNITED STATES POSTAL SERVICE – USPS

c) INFECTIOUS SUBSTANCE: Domestic Mail

NOTE: The USPS will accept those Infectious Substances permitted to be mailed within specific quantity limits and packaging conditions specified in 346 of the Hazardous, Restricted, and Perishable Mail Regulations, Publication 52, (see USPS Packing Instruction 6B), and the Domestic Mail Manual Regulation CO23.8.0, for Infectious Substances.

MAILABILITY:

- **International Mail:** Only as permitted when written approval has been granted prior to mailing.
- **Domestic Mail:** Permitted only via **Express Mail, Priority Mail, or First-Class Mail** service. Any infectious substance on the CDC listing of select agents, (42 CFR 72.3) must be sent by registered mail service.

MANDATORY PACKAGING REQUIREMENTS (Separate conditions apply to Domestic and International Mail as noted):

For Domestic Mail:

- A watertight primary receptacle (test tube, vial, etc.), must be durable and securely sealed.
- The primary receptacle must be capable of withstanding, without leakage, an internal pressure and temperature as required by 49 CFR 173.196 of the DOT Regulations.
- Multiple primary receptacles are permitted provided the total liquid volume of the infectious substance in all enclosed primary receptacles does not exceed 50 mL per mailpiece.
- Enough cushioning material must surround the primary receptacle and be sufficient to withstand shock, pressure changes, and prevent breakage.
- The space between the primary receptacle(s) and the secondary packaging at the top, bottom, and sides must contain enough material to absorb the entire contents of the primary receptacle(s) in case of leakage or breakage.
- A watertight secondary packaging with a leakproof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle and a secure sealing method.
- The secondary receptacle must be capable of withstanding, without leakage, an internal pressure and temperature as required by 49 CFR 173.196 of the DOT Regulations.
- A sturdy third package or outer container, meeting proper UN specifications (a fiberboard box or container of equivalent strength), must be used to enclose the primary receptacle(s) and the secondary packaging.
- No external surface of the outer packaging may be less than 3.9 inches wide (100 mm) as required by 49 CFR 173.196, DOT Regulations.

- Each mailpiece must be designed and constructed so that, if it were subject to the environmental and test conditions in 49 CFR 178.609, DOT Regulations, there would be no significant reduction in the effectiveness of the packaging.

SPECIAL MARKING REQUIREMENTS:

- The full name and address of the shipper (**From**) and the Consignee (**To**) on the top or side of the package.
- The proper shipping name and UN Number, “**Infectious Substances Affecting Animals, UN2900**” or “**Infectious Substances Affecting Humans, UN 2814**” must be clearly marked on the address side

SPECIAL LABELING REQUIREMENTS:

- The address side of the outer package must contain the Etiologic Agent/ Biohazard Material Label.
- **Labels of orientation** must be used for **liquid** samples to properly indicate upright position of receptacle(s).
- The DOT Hazard Class 6 warning label for **infectious substances**.

SPECIAL SHIPPING REQUIREMENTS:

- A properly completed **Shipper’s Declaration for Dangerous Goods** is required and must be prepared in **triplicate** and affixed to the outside of the outer packaging.

III. UNITED STATES POSTAL SERVICE-USPS

d) INFECTIOUS SUBSTANCE: International Mail

MANDATORY PACKAGING REQUIREMENTS:

For International Mail:

Infectious and noninfectious biological substances are permitted in international mail subject to the provisions that apply to domestic mail as noted in the aforementioned regulations. In addition, the following conditions apply:

- Biological substances are prohibited from international mail by certain countries. To determine if a prohibition exists for a specific country, **check the Individual Country Listings** in the International Mail Manual Regulations, 135-139.
- **Biological substances, including those containing pathogens, must be sent as registered airmail letter packages.**
- Biological substances can be sent to or received by only the following types of institutions when permission has been granted:
 - a. Laboratories of local, state, and federal government agencies.
 - b. Laboratories of federally licensed manufacturers of biological products derived from bacteria and viruses.
 - c. Laboratories affiliated with or operated by hospitals, universities, research facilities, and other teaching institutions.
 - d. Private laboratories licensed, certified, recognized, or approved by a public authority.
- **Permission to mail biological substances must be obtained prior to mailing.** Qualifying institutions must submit a written letter of application on its organizational letterhead to the following:

MANAGER

INTERNATIONAL PRICING COSTING AND CLASSIFICATION

INTERNATIONAL BUSINESS UNIT

US POSTAL SERVICE

475 L’ENFANT PLZ SW 370 IBU

WASHINGTON, DC 20260-6500

- The application must state the institution’s nature of work, the identity and qualifications of the prospective recipient, and the number of packages to be mailed.
- **Upon approval, the requisite number of biological substance mailing labels will be furnished to the mailer by the Postal Service.**
- **Mailable infectious biological substances are limited to 50 mL per mailpiece** and must be packaged in accordance with **Packaging Instruction 6B**, as well as in accordance with DMM CO23.8.3 and the additional requirements in IMM 135.31 and 135.41.
- A shipper’s declaration for dangerous goods is required for air transportation.

III. UNITED STATES POSTAL SERVICE-USPS

e) Dry Ice

(PACKING INSTRUCTION 9A, USPS):

- Articles that include dry ice as a refrigerant for infectious substances must meet the requirements of 42 CFR 72.3 (c) and 49 CFR 173.196(e)(2)(ii).
- The outer package must permit the release of carbon dioxide gas.
- The packaging components should meet UN Specifications.
- The dry ice must be placed outside the secondary receptacle.
- Never place dry ice inside a sealed container.
- Place the dry ice between the secondary container and the outer shipping receptacle.
- Place shock-absorbent material in such a way that the secondary receptacle does not become loose inside the outer packaging as the dry ice dissipates.
- Mark the proper name and UN Number of dry ice on the appropriate side of the outer package, **Carbon dioxide, Solid; UN 1845**.
- Mark the net **weight of dry ice, in kilograms**, on the outside of the outer package.
- For surface transportation each mailpiece must be clearly marked **“Surface Mail Only”**.
- Label using a hazard label for dry ice, **Miscellaneous, Class 9**.

Dry Ice Mailability:

- International Mail. Dry ice is prohibited.
- Domestic Mail via Air Transportation, i.e., Express Mail, Priority Mail or First-Class Mail, dry ice is permitted in quantities of up to 5 pounds per mailpiece.
- Domestic Mail via Surface Transportation, i.e., Standard Mail; a mailpiece may contain more than 5 pounds of dry ice.
- Prepare mailpieces using packing instruction 9A

NOTE: A mailpiece packaged for surface transportation must not, under any circumstances, be routed via air transportation.

III. UNITED STATES POSTAL SERVICE – USPS

f) DRIED BLOOD SPECIMENS:

Clinical specimens collected by carefully applying a few drops of blood, freshly drawn by finger stick or heel prick with a lancet, onto absorbent specimen collection (filter) paper.

Diagnostic Sample:

- Dried blood spot specimens can be shipped or transported with no reasonable expectations of occupational exposure to blood or other potentially infectious material. See **CDC Guidelines for the Shipment of Dried Blood Spot Specimens**, page 3, Risk Evaluation.
- After drying, enclose standard filter paper collection kits (each kit contains a sturdy paper overlay that covers the absorbent filter paper containing the dried specimen), in a high quality bond envelope or paper mailer and seal.
- Paper mailers should be extra-strong, tear-proof, air-permeable, and water-resistant envelopes.
- Mark the outside of the envelope “Dried Clinical Specimens” or “Newborn Screening/Dried Clinical Specimen”.
- Do not use leak-proof plastic bags because heat buildup and accumulation of moisture within the bag may adversely affect the dried specimen and /or the test results.

Infectious Substance:

- See packaging requirements of the United States Postal Service.

For more information see the following references:**US Postal Service Domestic Mail Manual, Issue 52, dated 07/01/97, Regulation CO23.10.7, Hazardous Matter.**

Guidelines for the Shipment of Dried Blood Spot Specimens, Safety & Health Monograph, Office of Health and Safety, Centers for Disease Control and Prevention (CDC), May 1993.

Procedure for the handling and transport of diagnostic specimens and etiologic agents, Third edition, Approved standard. NCCLS document H5-A3. NCCLS, Wayne, PA, May 1994.

For more information on shipping diagnostic specimens and infectious substances via the United States Postal Service call your local Post Office. Website: (www.usps.com)

IV. INTERNATIONAL AIR TRANSPORT ASSOCIATION - IATA**a) DIAGNOSTIC SPECIMEN: Packing Instruction 650**

Non-pathogenic human or animal material including but not limited to blood and its components, excreta, secretia, tissue and tissue fluids shipped for diagnosis. Materials used for diagnostic screening tests (non-pathogenic, clinical blood specimens) are considered Diagnostic Specimens. Live animals are not included in this category.

Packing Instruction 650

Operator Variations: 2.9.3 Variations filed with IATA, more restrictive than IATA regulations and applicable to all transportation performed by the operators concerned.

➤ CO-07 Continental Airlines:

Division 6.2, Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.

➤ CO-08 Continental Airlines:

All international and domestic inter-line shipments of dangerous goods, as defined by the Regulations, must be booked with Continental Airlines' Customer Service Center.

➤ CS-07 Continental Micronesia:

Division 6.2 Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.

➤ FX-09 Federal Express:

Division 6.2, Risk Group 4 will not be accepted for carriage.

➤ QF-05 Quantas:

Diagnostic Specimens packed in accordance with Packing Instruction 650 are not permitted in the passenger cabin and must be lodged as cargo.

MANDATORY PACKAGING REQUIREMENTS:

- A watertight primary receptacle(s) – for diagnostic specimens the maximum net quantity must not exceed 500 mL.
- For substances shipped at ambient temperatures or higher, primary receptacles include glass, metal or plastic. Positive means of ensuring leak-proof seal, such as heat seal, skirted stopped or metal crimp seal must be provided. If screw caps are used they must be reinforced with adhesive tape.
- Primary receptacles must be individually wrapped to prevent contact.
- A watertight secondary packaging – the maximum quantity per outer packaging for diagnostic specimens must not exceed 4 L.

- Absorbent material, capable of absorbing the entire contents, must be placed between the primary and the secondary packaging.
- No absorbent material is required when shipping solid substances.
- Enough absorbent material must be used to absorb the entire contents of all of the primary receptacles.
- A sturdy third, outer container or package. Outer packages must be at least 100 mm (4 in.) in the smallest overall external dimension.
- The package size must accommodate all labels, markings and documentation.
- Packaging materials must be of good quality and construction. The outer packagings must pass the drop test.
- An itemized list of all contents must be enclosed between the secondary packaging and the outer packaging.

SPECIAL MARKING REQUIREMENTS:

- Diagnostic Specimens Packed in Accordance With IATA Packing Instruction 650" must be clearly marked on the outside of each package.
- Full name and address of the shipper (**From**) and the Consignee (**To**) must be marked on the top or side of the package.

SPECIAL LABELING REQUIREMENTS:

- The outside of the third container must contain the International Biohazard Symbol **Label** with either a fluorescent orange or fluorescent red background. This label must be on containers used for shipping human blood, human blood products, unfixed human tissues, semen, fluids from body cavities and joints, as well as any human body fluids containing visible blood.
- **Labels of orientation** must be used for **liquid** samples.

SPECIAL SHIPPING REQUIREMENTS:

- Enclose a completed **Air Waybill**.
- The "**Nature and Quantity of Goods**" box of the air waybill must show the text **DIAGNOSTIC SPECIMENS PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650'**
- A Shipper's Declaration for Dangerous Goods is **NOT** required.

SPECIFIC SHIPPING REQUIREMENTS:

Substances shipped refrigerated or frozen using wet ice, prefrozen packs, Carbon dioxide, solid (dry ice) or other refrigerant:

- The refrigerant must be placed outside the secondary packaging or in an overpack with one or more completed packagings.
- Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated.
- If ice is used the packaging must be leak-proof.
- If Carbon dioxide, solid (dry ice) is used the outer packaging must permit the release of carbon-dioxide gas.
- The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

Substances shipped in liquid nitrogen:

- Plastic capable of withstanding very low temperatures must be used instead of glass receptacles.
- Secondary packaging must also withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles.
- Requirements for shipment of liquid nitrogen must also be observed.
- The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

Lyophilized substances:

- Primary receptacles must be flame sealed glass ampoules or rubber-stoppered glass vials with metal seals.

IV. INTERNATIONAL AIR TRANSPORT ASSOCIATION - IATA

b) INFECTIOUS SUBSTANCE: Packing Instruction 602

Substances known to contain, or reasonably expected to contain pathogens suspected to cause disease in humans or animals. These substances can be human or animal material including but not limited to blood and its components, excreta, secreta, tissue and tissue fluids. Substances shipped for confirmatory testing, known or suspected to contain infectious substances are regulated as Infectious Substances.

Packing Instruction 602

State Variations: 2.9.1 Variations filed with IACO and IATA, more restrictive than IATA regulations and apply to the transport of dangerous goods by air.

- **AUG-03 Australia:**
Infectious substances other than human blood products, human urine and human tissue, are prohibited from entry to Australia without prior approval from the Australian Health Authorities.
- **CAG-04 Canada:**
Infectious substances are not permitted in the mail in Canada. Infectious substances must documentation and labelling requirements including the requirements outlined in 1.3.3.1 of the IATA Regulations.
- **USG-13 United States:**
A copy of the Shipper's Declaration must be retained by the operator for not less than 90 days. to, or leakage from, a package containing infectious substances within the United States, the Center for Disease Control (CDC) in Atlanta, Georgia, must be notified immediately at the following telephone number: 1-(404) 633-5313.
- **VUG-02 Vanuatu:**
Infectious substances are prohibited from entry to Vanuatu without prior approval from the Vanuatu Government Department of Health. (Director of Health/P.O. Box 102/Port-Vila/Vanuatu)

Operator Variations: 2.9.3 Variations filed with IATA, more restrictive than IATA regulations and applicable to all transportation performed by the operators concerned.

- **5X-04 United Parcel Service:**
The following classes/divisions of dangerous goods are prohibited from UPS international small package and Air Cargo services under any circumstances: Division 6.2, (Infectious Substances).
- **AF-04 Air France:**
All blood extracts and biological samples, human or animal origin, must be classified as UN 2814, Infectious substance, affecting humans, liquid form in Division 6.2 and packed according to Packing Instruction 602. The exception would be safe human blood destined for treatment or transfusion for humans or blood plasma. The shipment and air waybill must be classified as non-dangerous pharmaceuticals, life-saving drugs.
- **AS-02 Alaska Airlines:**
Division 6.1, no substance required to bear a "Toxic" label will be accepted for discharge.
- **AS-08 Alaska Airlines:**
Division 6.2 Infectious substances (other than those substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U. S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.
- **CI-01 China Airlines:**
consignment of dangerous goods as shown in Subsection 4.2 of the IATA Regulations will not be accepted for carriage by China Airlines on its international passenger flights and domestic flights.
- **CO-07 Continental Airlines:**
Division 6.2, Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.
- **CO-08 Continental Airlines:**
All international and domestic inter-line shipments of dangerous goods, as defined by the Regulations, must be booked with Continental Airlines' Customer Service Center.

- **CS-07 Continental Micronesia:**
Division 6.2 Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.
- **FX-09 Federal Express:**
Division 6.2, Risk Group 4 will not be accepted for carriage.
- **SW-01 Air Namibia:**
Dangerous goods, as defined in IATA Regulations, will not be accepted for carriage on the Beechcraft B1900 Aircraft.
- **US-08 US Airways, Inc.:**
Division 6.2 Infectious Substances will not be accepted when the per package limit exceeds 50 mL per package.

MANDATORY PACKAGING REQUIREMENTS:

- A watertight primary receptacle(s). All primary receptacles must have positive closures (such as screw-on, snap-on or push-on caps) that must be taped.
- A watertight secondary container or packaging.
- An absorbent material must be placed between the primary receptacle(s) and the secondary packaging to absorb any liquid being shipped.
- If multiple primary receptacles are placed in the same secondary receptacle, they must be individually wrapped (or for infectious substances transported in liquid nitrogen), separated and supported, to prevent contact between them.
- Use enough absorbent material to absorb the entire contents of all of the primary receptacles.
- Absorbent material is not required for solid substances.
- A sturdy third, outer container or package consisting of corrugated fiberboard, wood, metal or rigid plastic. The outer packaging must be of sufficient strength to meet the design type tests in Subsection 6.5 and bear the specification markings.
- All packing materials must meet **UN Specifications for Division 6.2 Infectious Substances**.
- The outer package must be large enough in size to accommodate all markings, labelling and documentation.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
- Packages must be at least 100 mm (4in) in the smallest overall external dimension.

SPECIAL MARKING REQUIREMENTS:

Note: IATA recommends markings be at least 12mm high, except packages of 30L or 30kg capacity or less must be 6 mm minimum height.

- The **Proper Shipping Name** (with the technical name). Example, **Infectious substance, affecting humans, (Hepatitis B Virus)**.
- The **UN Number**, example **UN 2814**
- **Full name and address** of the shipper (**From**) and the Consignee (**To**) marked on the top or side of the package.
- The **name and telephone number** of a person **responsible** for the shipment must be marked durably and legibly on the outer packaging.
- The package must be marked if using dry ice, (**Carbon dioxide, solid**), **UN 1845**.
- The **net weight** of dry ice in the package must be recorded on the outside of the outer package.
- The outside of the outer package must bear the markings that clearly identify the package as one that meets **UN Specifications for Division 6.2 Infectious Substances**.
- Overpacks containing Dry Ice must state “**Inner Packages Comply with Prescribed Specifications**”.

SPECIAL LABELING REQUIREMENTS:

- Arrows or **Package Orientation Labels** are required on combination packages containing liquid. (An exception is infectious substances in primary receptacles of 50 mL or less). When arrows are required, there must be two, one on opposite sides of the package.
- **Hazard label for Infectious Substances, Class 6**.
- **Hazard label for Dry Ice, Miscellaneous, Class 9**, if used.

- **Cargo Aircraft Only label**, as it applies. When shipping more than 50 mL or 50 g of infectious substance, you need to use the Cargo Aircraft only label, as the shipment will be restricted to cargo. Cross off passenger and cargo on the shipper's declaration. If shipping less than 50 mL or 50 g, you do not need a cargo label and you need to cross off cargo only on the documentation.

SPECIAL SHIPPING REQUIREMENTS:

- **The shipper must make advance arrangements with the consignee and the operator** (carrier), to ensure that the shipment can be transported and delivered without delay.
- The following required statement (8.1.6.11.3) must be included in the Additional Handling Information area of the Shipper's Declaration: **"Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made"**.
- **Complete** and attach a **Shippers Declaration**, place it to a pouch, and attach the pouch to the outside of the outer package.

SPECIFIC SHIPPING REQUIREMENTS:

Substances shipped refrigerated or frozen using wet ice, prefrozen packs, Carbon dioxide, solid (dry ice) or other refrigerant:

- The refrigerant must be placed outside the secondary packaging or in an overpack with one or more completed packagings.
- Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated.
- If ice is used the packaging must be leak-proof.
- If Carbon dioxide, solid (dry ice) is used the outer packaging must permit the release of Carbon-dioxide gas.
- The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

Substances shipped at ambient or higher temperatures:

- Primary receptacles may only be of glass, metal or plastic. Positive means of ensuring a leak-proof seal must be provided, such as heat seal, skirted stopper or metal crimp seal. If screw caps are used, these must be reinforced with adhesive tape.

**For more information and technical assistance with Dangerous Goods call The Dangerous Goods International at 904-491-0925, or fax at 904-491-0989, Website: (www.dgitraining.com)
IATA telephone number: 514-390-6757, IATA fax 514-874-2660**

WEB SITES FOR LISTINGS OF INFECTIOUS SUBSTANCES BY RISK GROUP:

- <http://www.tc.gc.ca/acts/regs>
- <http://www.absa.org/riskgroups/index.html>
- <http://www.hc-sc.gc.ca/hpd/lcdc/biosafety/docs/index.html>

PROCEDURE FOR THE TRANSFER OF SELECT AGENTS FOR NON-EXEMPTED LABORATORIES

Summary: The Department of Health and Human Services has published regulations regarding the access, use and transfer of select agents for research purposes. Select agents are those biological agents that have the potential to pose a severe threat to public health and safety. The list of “Select Agents” includes approximately 40 viruses, bacteria, rickettsia, fungi and toxins whose transfer in the United States is controlled by The Centers for Disease Control and Prevention. See a listing of select agents in the attachment section at the end of this document.

The regulation, Title 42 CFR Part 72 .6, “Additional Requirements for Facilities Transferring or Receiving Select Agents”, was designed to ensure the following:

- that infectious agents and toxins listed as select agents are shipped only to institutions or individuals registered with CDC or CLIA-certified who are equipped to handle select agents;
- that select agents are shipped only to those who have legitimate reasons to use them;
- and that the system implemented, whereby scientists and researchers involved in legitimate research involving transferring and receiving agents, could continue without undue burden.

Prior to the transfer of select agents, both the facility shipping the select agent (shipper/transferor) as well as the facility receiving the select agent (consignee/requestor) must be registered with CDC in Atlanta, Georgia unless they meet the requirements for exemption.

Research and clinical exemptions exist. Specific strains of some infectious agents and certain toxins are exempt for research purposes. Clinical specimens sent to Clinical Laboratories (CLIA certified) may also be exempt under certain conditions.

How to Register with CDC

To register with CDC, contact CDC, Office of Health and Safety, Laboratory Registration>Select Agent Transfer (LR/SAT) Program by one of the following means:

- a) By fax: 404-639-0880
- b) By e-mail: lrsat@cdc.gov
- c) By phone: 404-639-4419

The LR/SAT Program is responsible for both the registration and on-site inspection process to assure that the facility meets the biosafety level requirements for working with the select agent in question.

The facility must request an application package for select agents by fax or e-mail.

The facility must fill out the application request and return it to the CDC, LR/SAT Program.

CDC will contact the facility to review the application, clear up any questions pertaining to the application and arrange for the on-site inspection if necessary.

Each registered facility must have in place procedures for the disposal of select agents on-site.

Each registered facility must designate a responsible facility official (RFO) to oversee the process which includes signing each request certifying that the consignee is affiliated with the requesting facility and that the laboratory meets the biosafety requirements and guidelines for working with the requested agent.

Registered facilities are issued a registration number that must be used as a part of the transfer process from one facility to another. CDC sends a registered certification along with CDC form EA-101. These are sent to the facility by fax and by U. S. Mail.

How to use CDC Form EA-101

Form (CDC) EA-101, the required documentation necessary for the transfer of select agents, must be completed for each transfer of a select agent. A paper copy must be kept by the RFO for a minimum of five years or the RFO must retain the record 5 years after the agent is consumed, exhausted or destroyed, whichever is longer.

Shipment of a select agent to the consignee:

1. The shipper's RFO must verify with the consignee's RFO, and if necessary, with CDC, that the requesting facility:
 - a) maintains a valid and current registration for the select agent being requested;
 - b) that the person requesting the select agent is an employee of the requesting facility and that;
 - c) the proposed use of the agent by the requestor is correctly indicated on form EA-101.

NOTE: CDC recognizes that the select agent registration certificate does not contain information regarding which specific select agent(s) a facility is registered for. Contact CDC for verification:

- if the sender cannot verify the registration status of the consignee;
- if there is any suspicion that the agent may not be used for the requested purpose;
- if there are any other concerns.

2. After the shipper verifies the above information, he/she fills in blocks 1 and 2 of the EA-101 and properly packages the material for shipment to the consignee.
3. Select agents must be packaged, marked, labeled and shipped in accordance with all federal (42 CFR 72 and 49 CFR 100-180) and international (IATA) regulations.
4. The shipper should utilize a mechanism for tracking the select agents shipped.
 - Call ahead to notify the consignee of the shipping date.
 - Have the consignee notify the shipper by phone or e-mail within 36 hours that the package was received intact and on what date the package was received.
 - Record this information for record purposes.
 - A return receipt is required by law for select agents listed in 42 CFR Part 72.3. See the listing of these agents in the attachment section at the end of this document.
5. The shipper also fills out Section 3 and the shipping information in Section 4, including the date of shipment.

Receipt of the select agent by the consignee:

1. The consignee's RFO must acknowledge receipt of the agent to the shipper electronically or by phone within 36 hours of receipt.
2. The consignee's RFO is required to provide a paper copy or facsimile transmission of receipt to the sender within three business days of the receipt.

Submitting form EA-101 to CDC:

1. After acknowledgement of the receipt by the consignee, the shipper writes in the date the agent was received in block 4 of form EA-101.
2. The shipper must provide a completed paper copy or FAX of form EA-101 within 24 hours to CDC.
3. A completed copy of form EA-101 is sent to the consignee at the same time.

Destruction or depletion of a transferred select agent:

1. The RFO of the facility must complete Section 5 of EA-101.
2. A copy or FAX of EA-101 must be sent to CDC

PROCEDURE FOR THE TRANSFER OF SELECT AGENTS BETWEEN CLIA-CERTIFIED AND NON-EXEMPTED LABS

Since CLIA-certified laboratories using select agents for exempt purposes are not required to register with CDC, CDC cannot verify that a CLIA laboratory is authorized to receive, or is capable of handling a select agent. When a registered facility receives a request from a CLIA-certified laboratory for a select agent, CDC recommends the following:

- the CLIA laboratory must provide the non-CLIA laboratory with a copy of their current CLIA certificate;
- the CLIA laboratory must provide the non-CLIA laboratory with a signed statement that their facility is capable of safely handling the select agent in question;
- the CLIA laboratory must verify in writing that the select agent will only be used for the purposes that are exempt from the regulation.

PROCEDURE FOR THE TRANSFER OF SELECT AGENTS FOR EXEMPTED CLIA-CERTIFIED LABORATORIES

Summary: Regulation, 42 CFR 72.6, specifically exempts from the provisions of Section 72.6 clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA) that utilize select agents for the following:

- Diagnostic purposes
- Reference purposes
- Verification purposes
- Proficiency testing purposes

The regulation provides procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from CLIA laboratories. No additional paperwork on behalf of CLIA laboratories is required by the regulation. CDC will accept a CLIA certification number on CDC Form EA-101 in lieu of the required assigned registration number.

Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions:

1. Prior to shipping a select agent to a CLIA laboratory, the shipper (transferor) must:

- a. Provide the following information on CDC Form EA-101:
 - The name of the consignee and the requesting facility;
 - The name of the shipper and the transferring facility;
 - The name of the shipper's responsible facility official ;
 - The consignee facility's CLIA certification number (which the shipper must verify with the registering entity as being valid and current);
 - The shipper's facility's registration number;
 - The name of the select agent(s) being shipped;
 - The proposed use of the select agent(s);
 - The quantity (i.e., the number of containers and the amount per each container) of the select agent(s) being shipped.
- b. Verify receipt of the select agent with the CLIA laboratory and note the receipt on CDC Form EA-101
- c. Transmit by FAX a copy of the form, signed by the shipper and the shipper's RFO to the registering entity holding the registration of the shipper's facility, (CDC).
- d. There are three copies to Form EA-101; one copy stays with the shipper, one copy is sent to the consignee and one copy is sent to CDC.
- e. Retain a copy of Form EA-101. A paper copy must be kept by the shipper's RFO for a minimum of five years or the RFO must retain the record 5 years after the agent is consumed, exhausted or destroyed, whichever is longer.

2. Prior to receiving a select agent from a CLIA laboratory, the consignee must be registered in accordance with Section 72.6 (a) and comply with the following requirements:

- a. Provide the following information on CDC Form EA-101:
 - The name of the consignee and the requesting facility;
 - The name of the shipper and the transferring facility;
 - The name of the consignee's responsible facility official;
 - The CLIA certification number of the shipper's facility;
 - The consignee's registration number for the facility;
 - The name of the select agent(s) being shipped;
 - The proposed use of the select agent(s);
 - The quantity (i.e., the number of containers and the amount per each container) of the select agent(s) being shipped.
- b. Upon receiving the agent, the consignee notes the date of receipt on Form EA-101.
- c. The consignee must FAX a copy of Form EA-101, signed by the consignee and the consignee's RFO, to the registering entity holding the consignee facility's registration, CDC.
- d. The RFO retains a copy of Form EA-101 for a minimum of five years or the RFO must retain the record 5 years after the agent is consumed, exhausted or destroyed, whichever is longer.
- e. Complies with the disposal requirements of Section 72.6(i):
 - The RFO of the facility must complete Section 5 of EA-101.
 - A copy or FAX of Form EA-101 must be sent to CDC.

**DUTIES OF RESPECTIVE RESPONSIBLE FACILITY OFFICIALS (RFO) FOR FILLING
IN CDC FORM EA-101 FOR THE TRANSFER OF SELECT AGENTS**

CONSIGNEE RFO REQUESTOR RFO RECEIVER RFO	SHIPPER RFO TRANSFEROR RFO SENDER RFO
1. Completes agent description (Block 1)	
2. Completes requestor information (Block 2)	
3. Faxes Form EA-101 and registration certificate to shipper	
	4. Verifies registration information
	5. Completes shipper information
	6. Completes shipping/packing information
	7. Oversees packaging and shipment of agent to consignee (requestor). Sends shipment.
8. Receives select agent and records date	
9. Notifies shipper's (transferor's) RFO of receipt via FAX or Phone within 36 hours; provides paper copy within 3 days.	
	10. Shipper enters date select agent received by consignee in Block 4 of Form EA-101
	11. Shipper faxes completed Form EA-101 to CDC within 24 hours
12. Retains paper record for 5 years or 5 years after the agent is Used up or destroyed, whichever is longer.	12. Retains paper record for 5 years or 5 years after the agent is used up or destroyed, whichever is longer.
13. Record the date of consumption/destruction on Form EA-101 And FAX a copy to CDC	13. Record the date of consumption/destruction on Form EA-101 and FAX a copy to CDC

EXPORT OR IMPORT OF INFECTIOUS SUBSTANCES, AFFECTING HUMANS AND/OR INFECTIOUS SUBSTANCES, AFFECTING ANIMALS.

- Is an export license required to ship the organism?

In order to assess whether or not an export/import license is required for shipping the organism, look up the organism on the Commerce Control Listing established by the Department of Commerce in 15 CFR Parts 730 to 799. The listing can be found in Part 774, Section 774.1, Supplement No. 1 of the Export Administration Regulations.

The following excerpts from the Commerce Control Listing should be reviewed:

- ◆ **1C351** Infectious substances, affecting humans; human pathogens, zoonoses and toxins
- ◆ **1C352** Infectious substances, affecting animals; animal pathogens
- ◆ **1C353** DNA or genetically modified micro-organisms
- ◆ **1C354** Plant pathogens
- ◆ **1C991** Vaccines, immunotoxins and medical products

If the organism to be shipped is on any of the above lists, (NOTE: listings 1C351 and 1C352 include infectious substances), then an export license is required for international shipment.

- If an export license is required, contact the Department of Commerce, (DOC), Bureau of Export Administration at 202-482-4811 or through the internet at <http://www.bxa.fedworld.gov> or <http://www.bxa.doc.gov> for information on:
 1. obtaining a license, ECCN, (if needed);
 2. filling out the shipper's declaration and any other required paperwork which must accompany the shipper's declaration;
 3. electronic services; and
 4. obtaining forms by phone.
- ◆ For answers to specific questions regarding export / import licenses, contact Douglas Brown at 202-482-5808.
- Where is the organism being shipped? What is the exact country and location of destination? What documentation is required to accompany the organism? Some countries have restrictions and variances regarding export/import of infectious substances. Check with CDC, DOC, the Airline Carrier or Courier. Federal Express (Airline Carrier) will check out restrictions or variances and tell you exactly what documents are required as well as how to fill them out correctly. For assistance in this area call FedEx at 1-800-247-4747.
- Does the consignee need an import license? Are there any conditions regarding importing infectious substances attached to the specific license? Find out the above information by contacting the consignee directly by phone or e-mail. Ask the consignee to send by mail or fax, a copy of their import license complete with any attachments to the license. It is important to review all conditions set forth in the attachments to the license as these may include additional paperwork and documentation required from the shipper, which must accompany the international air waybill and shipper's declaration as a condition of transport. If you have questions contact the following sources for clarification:
 1. Contact CDC at 404-639-3354, (ask for Yvonne Stiffel), for information on obtaining export/import licenses, risk group classification and restrictions regarding export/import;
 2. Contact the Department of Commerce, Bureau of Export Administration for information on obtaining the license, ECCN, (if needed); filling out the shipper's declaration and any other required paperwork which must accompany the shipper's declaration; electronic services; and obtaining forms by phone; call 202-482-4811 or 949-660-0144. For answers to specific questions contact Douglas Brown at 202-482-5808.

The fax number for DOC is 202-482-3617. You may also contact DOC through the Internet at <http://www.bxa.fedworld.gov> or <http://www.bxa.doc.gov>

3. Contact the airline carrier of choice to review the conditions set forth in the license and ensure that you have all the proper paperwork required as a condition of transport.

- Note the proper shipping name, technical name and UN number of the organism. Example: if shipping *bordetella holmesii* the proper shipping name is **Infectious substance, affecting humans**, the technical name, which must appear in brackets under the proper shipping name, is (***Bordetella holmesii***), and the **UN** number is **2814**. This information must be marked clearly and uniformly on the outside of the outer package and on all required documentation as required by IATA, DOC, USPS, and courier specific regulations.

If shipping an organism that affects both humans and animals, ship the organism as Infectious substance, affecting humans.

- To what risk group does the organism belong? Check the **CDC or Transport Canada listings**, etc. for risk group classifications. If the organism is unclassified or there is doubt about the classification, package and ship the organism as an infectious substance.
- Is the organism on the **CDC List of Select Agents**? Check the CDC listing and follow the instructions for the select agent rule. Find out whether or not a form EA 101 is required. If you have questions pertaining to the select agent rule contact CDC at the following:
 1. By phone: 404-639-4418
404-639-4419 (Mark Hemphill)
 2. By fax: 404-639-0880
 3. By e-mail: lsrusat@cdc.gov
 4. By internet: <http://www.cdc.gov/od/ohs/lsrusat/applictn.htm>
- Is the organism on the **Specified Animal Pathogen List** in the Schedule to the Specified Animal Pathogens Order of 1998? Some import licenses may have this stipulation as a condition attached to the license. Check the listing at the end of this document.
- Examples of some documentation required by the airline carrier or as a condition to the import license:

Note: Documentation required may vary from country to country or from licensee to licensee within country, due to the conditions attached to the consignees specific import license.

1. **Shipper's Declaration or a Shipper's Export Declaration.**
2. A **Commercial Invoice**, the original and one copy are required to accompany the air waybill.
3. An **International Air waybill**.
4. A **letter to the international customs agent** which must be on official letterhead containing a complete description of the isolate, with a statement that the isolate is to be used for research purposes only.
5. The **"To Whom It May Concern" letter** on official letterhead stating that the culture is pure and free from all infectious agents listed in the **Schedule to the Specified Animal Pathogens Order of 1998**.
6. A **letter to the consignee** on official letterhead stating the contents of the package, the fact that the organism is to be used for research purposes only, and whom to contact should problems or questions arise concerning the isolate. Include the phone number and e-mail address of the shipper. This letter goes inside the outer packaging.

7. Documents numbered 1 through 5 should be included inside the document pouch which should be attached to the outside of the outer packaging in such a way as it does not obstruct or overlap any required markings or labels.
8. The required markings, labels and documentation will dictate the size of the outer packaging.

- What quantity is being shipped? The quantity will determine transport by passenger/cargo or cargo aircraft only. The maximum quantity per package of infectious substance allowed on a passenger and cargo aircraft is 50 mL, or 50 grams. The maximum quantity per package allowed on cargo aircraft only is 4 liters or 4 kilograms. The maximum quantity per package of diagnostic specimen allowed is 4 liters or 4 kilograms, (for both passenger and cargo or cargo aircraft only).
- If traveling by plane IATA Regulations prevail including identifying, classifying, packaging, marking, labeling and documenting. Use UN specified packagings for infectious substances, Class 6.2.
- It is **important to phone ahead and let the consignee know when the package is to be shipped** and by what airline, etc. It is equally important that the consignee **immediately notify the shipper upon receipt of the package**. The shipper should record the date of receipt by the consignee on the original consignment paperwork.

Some attachments which may be requested as a condition of transport:

- Commerce Control List
- Listing of Infectious Substances by Risk Group Classification, taken from the Canadian Transportation of Dangerous Goods Act
- CDC Listing of Select Agents
- Schedule to the Specified Animal Pathogens Order 1998
- Copy of an import license
- Copy of conditions attached to an import license
- Blank Commercial Invoice (The original and one copy must accompany the International Air waybill)
- Instructions for filling in the Commercial Invoice
- Sample of a completed Commercial Invoice non-specific
- Sample of a completed Commercial Invoice as it relates to infectious substances
- Blank Shipper's Declaration
- Instructions for filling out a Shipper's Declaration
- Completed Shipper's Declaration
- Completed International Air waybill
- Example of letter to International Customs Agent
- Example of a letter stating that the material is free of any infectious agents listed in the Schedule to the Specified Animal Pathogens Order of 1998 addressed to "Whom it may concern".
- Example of letter to consignee listing the contents and stating that the organism is to be used for research purposes only.

DOCUMENTATION:

Air Waybill: <http://www.fedex.com/us/government/airbill>

Dangerous Goods Airbill: <http://www.fedex.com/us/government/shippingdocs>

Shipper's Declaration: <http://www.fedex.com/us/government/shippingdocs>

Commercial Invoice: <http://www.fedex.com/us/government/international/documents>

International Air Waybill: <http://www.fedex.com/us/government/international/documents>

CDC Form EA-101 for Select Agents: lsrusat@cdc.gov

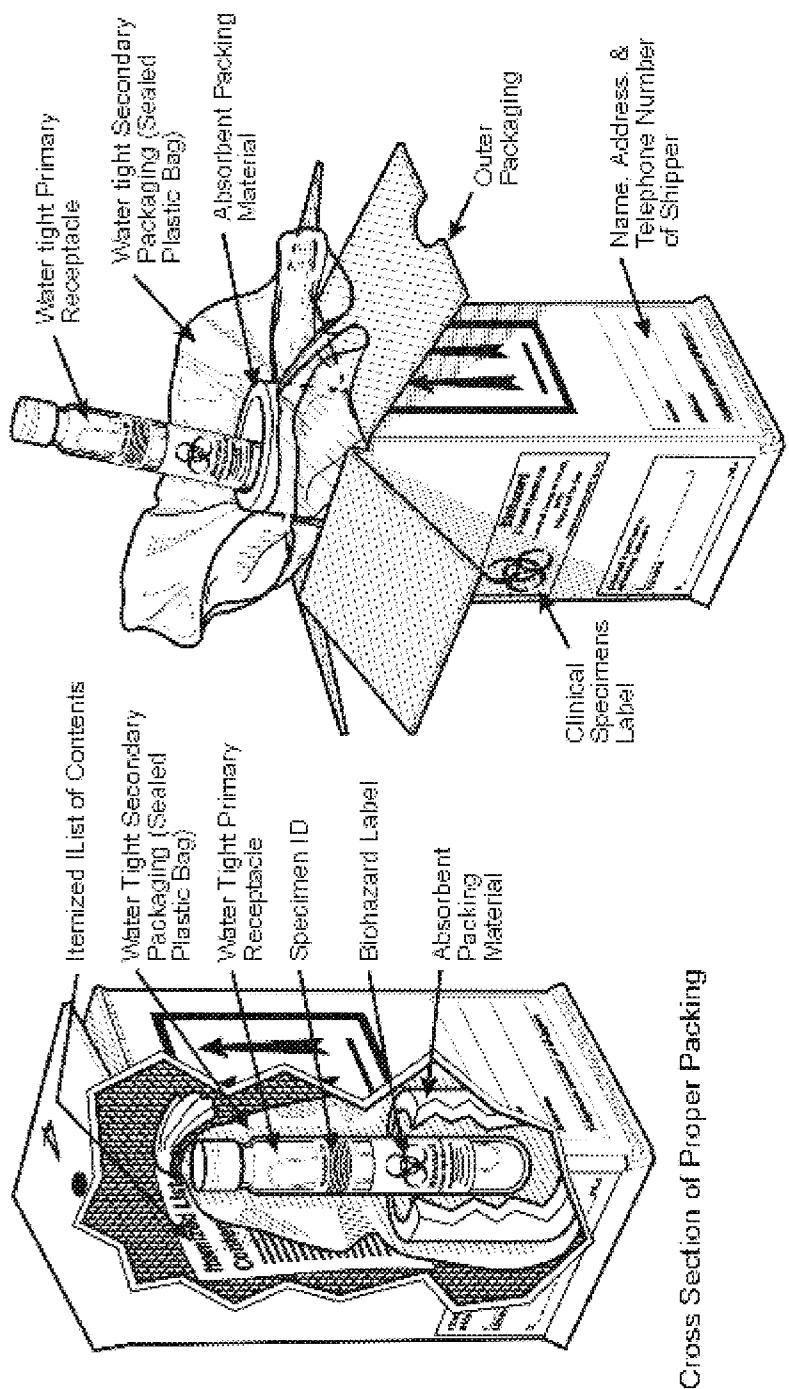
DIAGRAMS OF PACKINGS FOR SHIPMENT:

Clinical Diagnostic Specimen, (Triple Packaging System)

Infectious Substance, (Triple Packaging System, UN Specified Packagings)

Single Overpack, (Dry Ice)

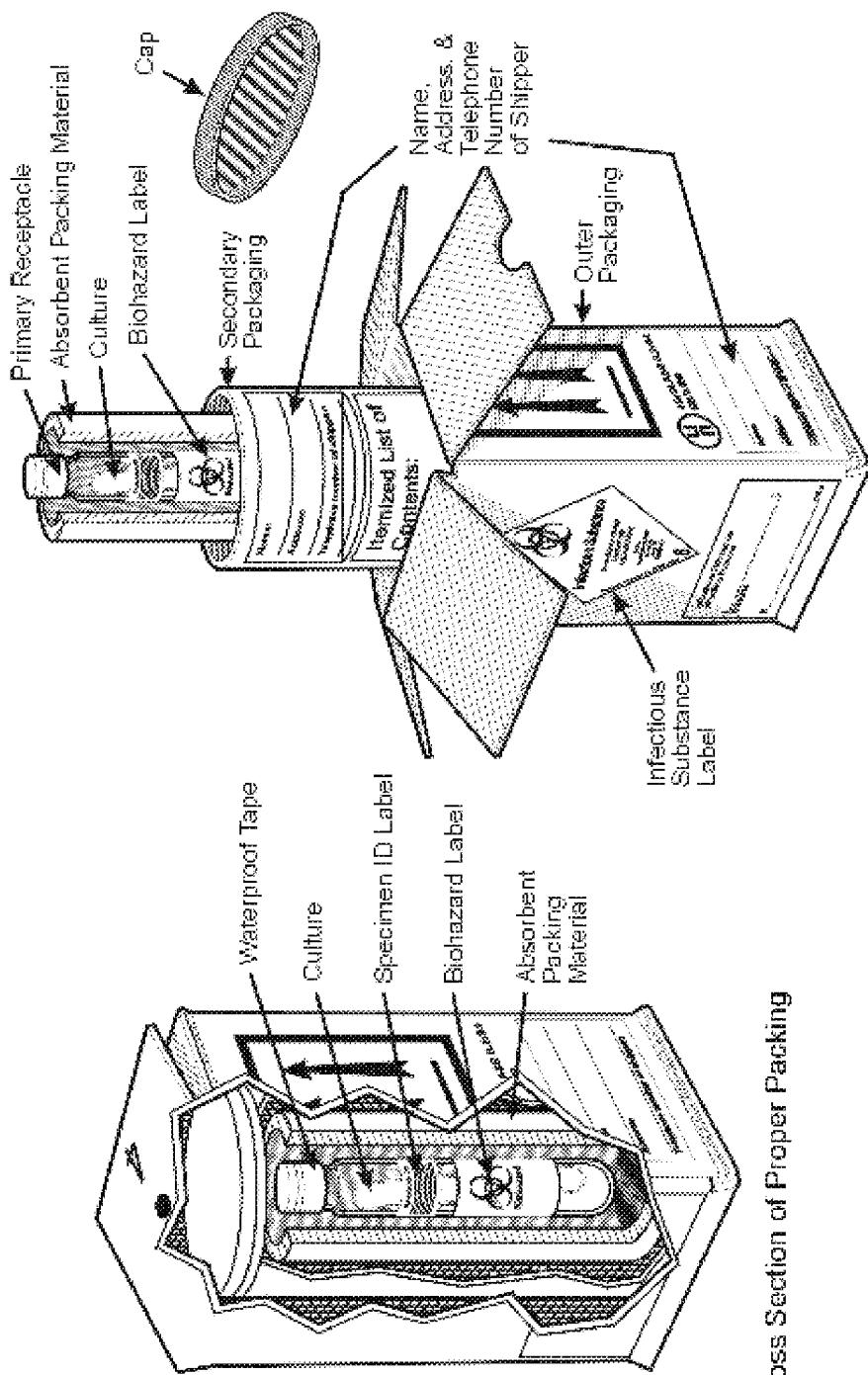
Multiple Overpack Shipper for Infectious Substances



Packing and Labeling of Clinical Specimens

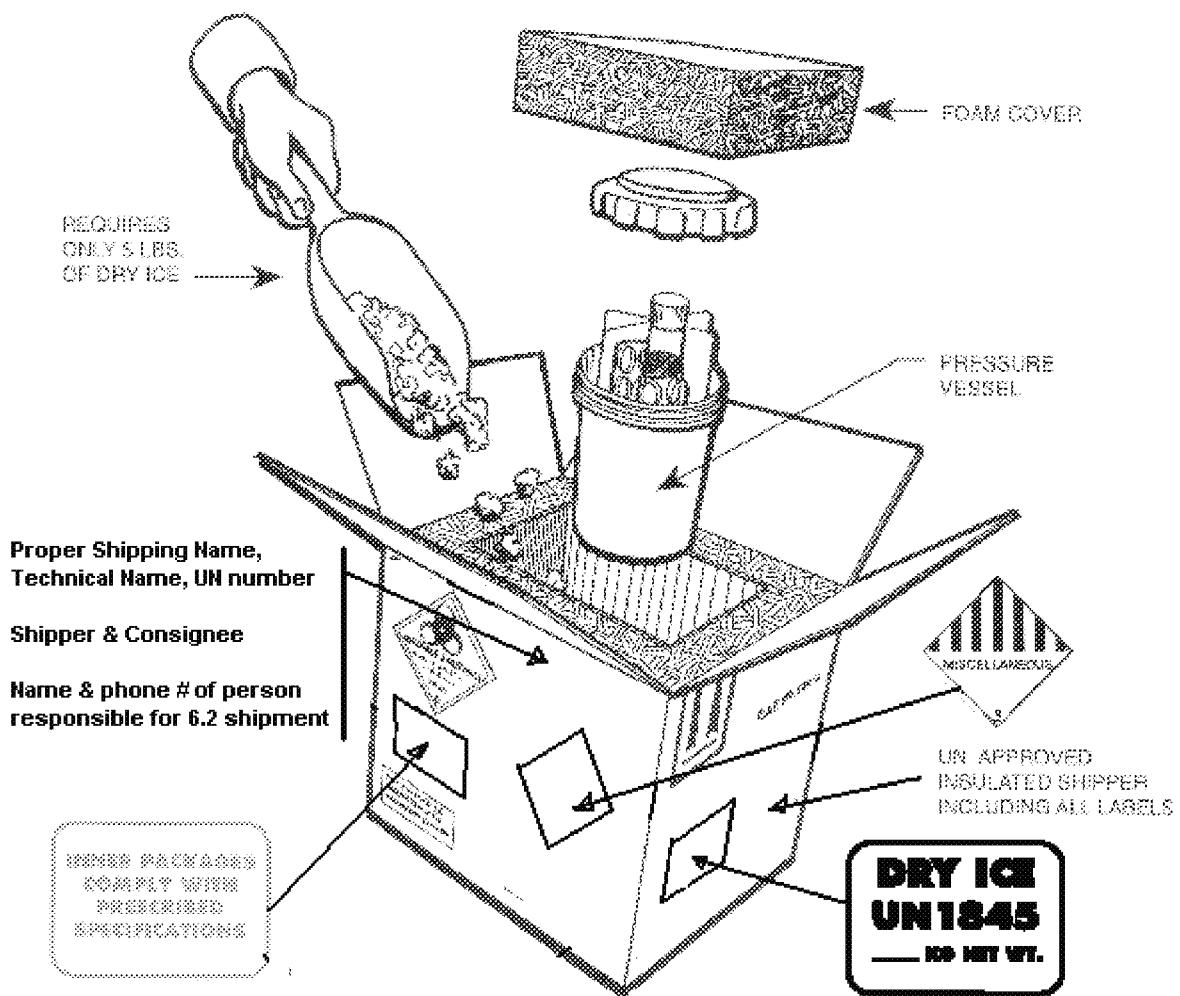
Packing and Labeling of Infectious Substances

Cross Section of Proper Packing



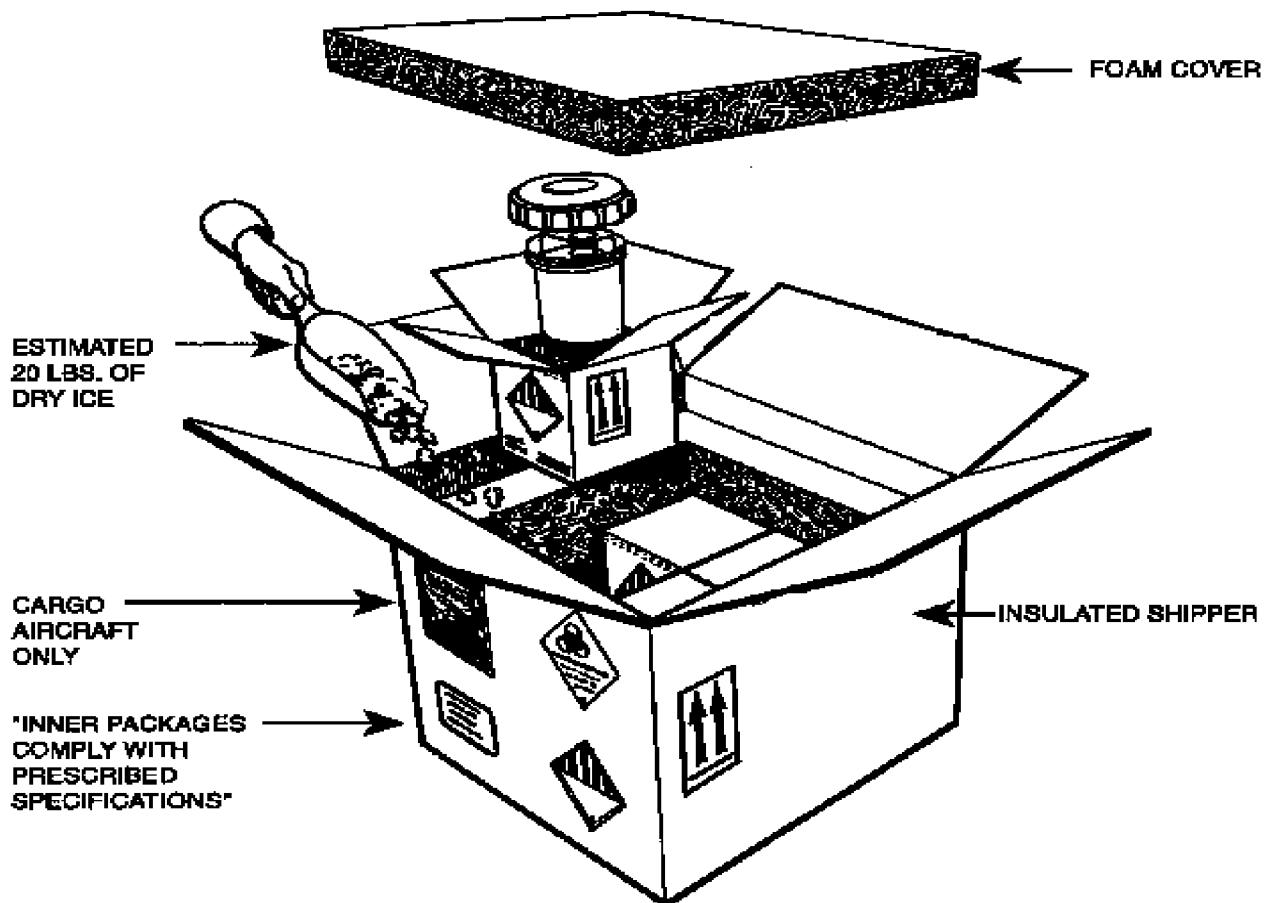
Infectious Substance, Dry Ice Overpack

for frozen or refrigerated specimens



Infectious Substance Overpack-Shipper

for frozen or refrigerated specimens



REGULATORY AGENCIES AND SOME CARRIERS OF DIAGNOSTIC SPECIMENS AND INFECTIOUS SUBSTANCES

AGENCY	REGULATIONS	INFECTIOUS SUBSTANCES	DIAGNOSTIC SPECIMENS
WORLD HEALTH ORGANIZATION (WHO) http://www.who.org	GUIDELINES FOR THE SAFE TRANSPORT OF INFECTIOUS SUBSTANCES AND DIAGNOSTIC SPECIMENS GENEVA, 1997 http://www.who.int/emc/biosafety http://www.absa.org/resources/Guides.htm	MUST MEET IATA PACKAGING REGULATIONS; INSTRUCTION 602; TRIPLE PKG. SYS.	MUST MEET IATA PACKAGING REGULATIONS; INSTRUCTION 650; TRIPLE PKG. SYS.
INTERNATIONAL CIVIL AVIATION ORGANIZATION (ICAO) http://www.icao.int	TECHNICAL INSTRUCTIONS FOR THE SAFE TRANSPORT OF DANGEROUS GOODS BY AIR; (DOC 9284-AN/905): 1997-1998 www.icao.int/icao/en/cat.htm	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 602 TRIPLE PKG. SYS.	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 650 TRIPLE PKG. SYS.
INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) www.iata.org	DANGEROUS GOODS REGULATIONS, 41 ST EDITION, 01/01/2000 http://www.dgitraining.com	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 602 TRIPLE PKG. SYS.	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 650 TRIPLE PKG. SYS.
UNITED STATES DEPARTMENT OF TRANSPORTATION (USDOT) http://www.dot.gov	CLASSIFICATION OF HAZARDOUS MATERIALS FOR TRANSPORTATION, TITLE 49 CODE OF FEDERAL REGULATIONS (PART 171-180) (49CFR Part 171-180), In Revision http://hazmat.dot.gov/rules/98_3971.htm	DOT REGULATION 49 CFR 173.196. ALSO USE CDC GUIDELINES USPHS 42 CFR PART 72	HAVE NO GUIDELINES OR REGULATIONS IN PLACE. NEW PROPOSED REGULATIONS DRAFTED 09/02/1998
UNITED STATES PUBLIC HEALTH SERVICE CENTER FOR DISEASE CONTROL AND PREVENTION (USPHS-CDC) http://www.cdc.gov	PACKAGING AND HANDLING OF INFECTIOUS SUBSTANCES AND SELECT AGENTS, TITLE 42 CODE OF FEDERAL REGULATIONS, PART 72; (42 CFR Part 72) In Revision www.access.gpo.gov/nara/cfr/cfr-table-search.html	DOT 49 CFR 173.196. REVISING CURRENT REGULATIONS FOR PACKAGING AND SHIPPING.	MINIMUM REQUIREMENTS. NEW PROPOSED REGULATIONS DRAFTED 10/28/1999.

AGENCY	REGULATIONS	INFECTIOUS SUBSTANCES	DIAGNOSTIC SPECIMENS
UNITED STATES POSTAL SERVICE (USPS) http://www.usps.gov	<p>REGULATED BY TITLE 39 CODE OF FEDERAL REGULATIONS, PART 111 (39 CFR Part 111). www.access.gpo.gov/nara/cfr/cfr-table-search.html</p> <p>SUBJECT TO RESTRICTIONS IN TITLE 18 UNITED STATES CODE 1716 (18 U.S.C. 1716).</p> <p>DOMESTIC MAIL MANUAL (DMM CO23).</p> <p>HAZARDOUS, RESTRICTED, AND PERISHABLE MAIL, PUBLICATION 52, JULY 1999.</p>	<p>USPS 39 CFR (Part 111)</p> <p>USPHS 42 CFR 72.3</p> <p>DOMESTIC MAIL MANUAL (DMM CO23).</p> <p>PUBLICATION 52, SECTION 346.212 TO 346.5, 1999</p>	<p>SUBJECT TO THE REQUIREMENTS OF THE DOMESTIC MAIL MANUAL CO23.8.4</p> <p>MAILABLE ITEMS MUST BE SENT AS EXPRESS, PRIORITY OR FIRST-CLASS MAIL.</p>
FEDERAL EXPRESS (FedEx) http://www.fedex.com	<p>FOLLOW IATA AND DOT REGULATIONS</p> <p>SEE SPECIFIC CARRIER INSTRUCTIONS</p> <p>http://www.fedex.com/us/services/</p>	<p>CHECK CDC LISTING FOR SELECT AGENTS</p> <p><u>ACCEPTABLE IF RISK GROUP 2 OR 3 AND PACKED ACCORDING TO IATA P.I. 602 FOR INFECTIOUS SUBSTANCES.</u></p>	<p>ACCEPTABLE IF PACKAGED ACCORDING TO IATA REGULATIONS. IATA PACKING INSTRUCTION 650. PACKAGE MUST CONTAIN BIOHAZARD LABEL.</p>
UNITED PARCEL SERVICE (UPS) http://www.ups.com	<p>FOLLOW DOT REGULATIONS</p> <p>DO NOT SHIP INTERNATIONALLY</p> <p>SEE SPECIFIC CARRIER INSTRUCTIONS</p>	NON-ACCEPTABLE	<p>MUST PACKAGE ACCORDING TO DOT REGULATIONS FOR INFECTIOUS SUBSTANCES. BIOHAZARD LABEL MUST BE ON PKG.</p>
LOCAL COURIER SERVICES	MUST FOLLOW DOT REGULATIONS		
CAB COMPANIES	MUST FOLLOW DOT REGULATIONS		

INTERNATIONAL AND NATIONAL WEBSITES:

AGENCY:	WEBSITE:	TELEPHONE:	FAX:
International Air Transport Association	www.iata.org www.iata.org/cargo/dg	514-390-6726 514-390-6770	514-874-9659
International Civil Aviation Organization	www.icao.org	514- 954-8022	514-954-6769
United States Department of Transportation	http://www.dot.gov	405-949-0036 ext. 374	405-946-4345
United States Department of Commerce Bureau of Export Administration	www.bra.fedworld.gov www.bxa.doc.gov www.access.gpo.gov	202-482-4811 202-482-5808 949-660-0144	202-482-3617
United States Public Health Service	www.usphs.gov		
The Centers For Disease Control	www.cdc.gov	404-639-3235 404-639-3354	404-639-2294
Laboratory Registration Select Agent Transfer Program/CDC	www.cdc.gov/od/ohs/irsat.htm	404-639-4418 404-639-4419	404-639-0880
United States Department of Agriculture	http://www.aphis.usda.gov/oa/ click on: imexdir.html		
Dangerous Goods International Training Center; Offer Training in IATA Regulations	www.dgitraining.com	800-338-2291 650-306-8450	650-306-8459
Federal Aviation Administration	www.faa.gov		
Federal Aviation Administration New England Regional Office	www.ane.faa.gov	781-238-7705 MA 860-623-5572 CT	781-238-7716 860-292-1360
Hazardous Materials Regulations (RSPA Ctr.) (Headquarters RSPA Center)	www.rspa.dot.gov	800-476-4922	202-366-3012
Hazardous Materials Safety	http://hazmat.dot.gov	202-366-4700 609-989-2256	202-366-2784 609-989-2277
Hazardous Materials Advisory Council, Washington, DC	www.hmac.org	800-634-1598 202-289-4550	202-289-4074
United States Postal Service	www.usps.gov	call your local P.O.	
Federal Express FedEx Dangerous Goods Hotline	www.fedex.com	800-463-3339 800-633-7019	
United Parcel Service, Hazardous Materials Support Center	www.ups.com	800-554-9964	

AGENCY:	WEBSITE:	TELEPHONE:	FAX:
Saf-T-Pak Offers course in shipping diagnostic Specimens and infectious substances According to IATA Regulations.	www.saftpak.com	800-814-7484 780-486-0211	780-486-0235 888-814-7484
Transportation Safety Institute (TSI) Offers course in DOT Regulations The course covers infectious substances, Biological products, diagnostic specimens And genetically modified organisms.	Http://www.tsi.dot.gov Www.text-trive.com/tsi	405-949-0036 ext 374	405-946-4345
Environmental Resource Center Offers course in DOT Regulations	www.ercweb.com	800-537-2372 919-469-1585	919-469-4137
State Laboratory Institute Massachusetts Department of Public Health	http://www.state.ma.us/dph/sli.htm	617-983-6656	617-983-6210
United Nations Sub-Committee of Experts	http://www.unece.org/trans (Click on reports)		
Transport Canada	www.tc.gc.ca Www.tc.gc.ca/acts/regs		
For information on classification of organisms according to risk:	www.absa.org/riskgroups/index.htm Or www.hc-sc.gc.ca/hpd/lcdc/biosafety/docs/index.html		

**SOME SUPPLIERS AND/OR MANUFACTURERS OF UN CERTIFIED PRODUCTS USED FOR
SHIPPING DIAGNOSTIC SPECIMENS AND INFECTIOUS SUBSTANCES:**

Action Pak, Inc.
2550 Pearl Buck Road
Bristol, PA 19007
Phone: 800-755-9764
Fax: 215-788-1760
Web: <http://www.actionpakin.com>

Casing Corporation
P.O. Box 820369
Dallas, TX 75382
Phone: 800-358-6866
Fax: 214-392-4418
Web: <http://www.casingcorp.com>

Air Sea Atlanta, Inc.
1234 Logan Circle
Atlanta, GA 30318
Phone: 404-351-8600
Fax: 404-351-4005
Web: <http://www.airseaatlanta.com>

Cin-Made Packaging Group, Inc.
1780 Dremnan Avenue
Cincinnati, Ohio 45223
Phone: 513-681-3600
Fax: 513-541-5945
E-mail: maryalice@cin-made.com
Web: www.cin-made.com

Air Sea Containers, Inc.
2749 NW 82nd Avenue
Miami, FL 33122
Phone: 888-272-9883
Fax: 305-599-1668
E-mail: sales@airsecontainers.com
Web: <http://www.airsecontainers.com>

The Compliance Center, Inc.
2150 Liberty Drive
Niagara Falls, NY 14304
Phone: 800-767-7231
Fax: 716-283-2764
Web: www.thecompliancecenter.com

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA. 15017
Phone: 800-245-2283
Fax: 412-257-3001
Web: <http://www.allpakin.com>

Dangerous Goods.Com
P O Box 60543
Houston, TX 77205
Phone: 281-821-0859
Fax: 281-821-6558
E-mail: larry@dangerousgoods.com
Web: www.dangerousgoods.com

Allflex Hazardous Material Packaging, Inc.
105 Race Street
Amber, PA 19002
Phone: 800-448-2467
Fax: 215-643-3339
E-mail: sales@allflex.com
Web: www.allflex.com

Dangerous Goods Management
14335-C Interdrive West
Houston, TX 77032
Phone: 281-442-8434
Fax: 281-442-6055
E-mail: jean@dgm-usa.com
Web: www.dgmsupport.com

Cargo Pak Corporation
3215 Wellington Court
Raleigh, NC
Phone: 800-266-0652
Fax: 919-878-9244
E-mail: rsmith@cargopac.com
Web: <http://www.cargopak.com>

DG Supplies, Inc.
28 C Industrial Drive
Hamilton, NJ 08619
Phone: 800-347-7879
Fax: 609-584-5744
E-mail: sales@dgsupplies.com
Web: <http://www.dgsupplies.com>

Environmental Packaging Sys. Ltd.
1 Research Drive
Dartmouth, NS, Canada B2Y 4M9
Phone: 800-277-8675
Fax: 902-466-6889
E-mail: akachar@ep-systems.ns.ca
Website: none

EXAKT Technologies, Inc.
7416 North Broadway Extension, Suite E
Oklahoma City, OK 73116
Phone: 800-866-7172
Fax: 405-848-7701
E-mail: infopak@exaktusa.co
Web: www.exaktpak.com

Federal Industries Corp.
2550 Niagara Lane
Plymouth, MN 55447
Phone: 800-523-9033
Fax: 612-476-8155
E-mail: chem-tran@aol.com
Web: www.chemtran.com

Freund Can Company
155 West 84th St.
Chicago, IL 60620
Phone: 773-224-4230
Fax: 773-224-8812
E-mail: customerservice@freundcan.com
Web: <http://www.freundcan.com>

General Container Corporation
P O Box 6140
Somerset, NJ 08875
Phone: 732-435-0020
Fax: 732-435-0040
E-mail: gencon@eclipse.net
Web: <http://www.generalcontainer.com>

Hazmatpac, Inc.
5301 Polk Avenue, Bldg. 18
Houston, TX 77023
Phone: 800-923-9123
Fax: 713-923-1111
E-mail: hazmatpac@hazmatpac.com
Web: <http://www.hazmatpac.com>

Industrial Crating & Packing, Inc.
P O Box 88299
Seattle, WA 98138
Phone: 425-226-9200
Fax: 425-226-9205
E-mail: indcrate@earthlink.net
Web: <http://www.indcrate.com>

Inmark, Inc.
P.O. Box 43309
220 Fisk Drive, SW
Atlanta, GA 30336
Phone: 404-267-2020
Fax: 404-267-2021
E-mail: sales@inmarkinc..com
Web: <http://www.inmarkinc.com>

LabelMaster
5724 North Pulaski Road
Chicago, IL 60646
Phone: 800-621-5808
Fax: 800-723-4327
E-mail: sales@labelmaster.com
Web: www.labelmaster.com

LPS Industries
10 Caesar Place
Moonachie, NJ 07074
Phone: 800-242-7628
Fax: 201-438-1326
E-mail:
Web: <http://www.psind.com>

Nefab Inc.
736 West Estes Ave.
Schaumburg, IL 60193
Phone: 847-985-1600
Fax: 847-985-3200
E-mail:
Web: <http://www.nefab.com>

O'Berk International, Inc.
3 Milltown Court
P.O. Box 1690
Union, NJ 07083
Phone: 800-577-7624
Fax: 908-687-5157
E-mail: obi@oberk.com
Web: <http://www.aluminiumbottles.com>

Polyfoam Packers Corporation
2320 Foster Avenue
Wheeling, IL 60090
Phone: 800-323-7442
Fax: 847-398-0653
E-mail: info@polyfoam.com
Web: <http://www.polyfoam.com>

ProPack, Inc.
76 Jansen Avenue
Essington, PA 19029
Phone: 610-521-4050
Fax: 610-521-8737
E-mail: dg.propack@erols.com
Web: <http://www.propack.com>

Russell-Stanley Corp.
685 Route 202/206
Bridgewater, NJ 08807
Phone: 908-203-9500
Fax: 908-203-1944
E-mail: info@russell-stanley.com
Web: www.russell-stanley.com

Saf-T-Pac, Inc.
101, 17872-106 Avenue
Edmonton, Alberta, Canada T5S 1V4
Phone: 800-841-7484
Fax: 780-486-0235
E-mail:
Web: <http://www.saftpak.com>

Source Packaging of New England, Inc.
405 F Kilvert Street
Warwick, RI 02866
Phone 800-200-0366
Fax: 401-738-7762
E-mail: sales@sourcepak.com
Web: <http://www.sourcepak.com>

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